

DISSERTATION ON
**“EVALUATION OF EFFICACY AND SAFETY OF MYOINOSITOL
IN WOMEN WITH POLYCYSTIC OVARIAN SYNDROME
TREATED AT A TERTIARY CARE HOSPITAL”**

Dissertation submitted to
THE TAMILNADU DR.M.G.R MEDICAL UNIVERSITY

In partial fulfilment of the regulations

For the award of the degree of

M.D PHARMACOLOGY - BRANCH-VI



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APRIL-2017

CERTIFICATE

This is to certify that this dissertation entitled “**EVALUATION OF EFFICACY AND SAFETY OF MYOINOSITOL IN WOMEN WITH POLYCYSTIC OVARIAN SYNDROME TREATED AT A TERTIARY CARE HOSPITAL**” is a bonafide research work of Dr.Chinthana. G in partial fulfilment of the requirements for M.D Branch-VI (Pharmacology) Examination of the Tamil Nadu Dr. M.G.R Medical University to be held in APRIL -2017. The period of study was from 2014-2017.

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INTRODUCTION

36 Polycystic ovarian syndrome (PCOS) or stein - leventhal syndrome is one of the most common endocrine disorders, affecting 20% of women in reproductive age^[1]. It is a complex multidimensional disorder with presence of polycystic ovaries in a women with cluster of symptoms which includes amenorrhoea, oligomenorrhoea, hirsutism, 42 anovulation and other signs of androgen excess such as acne and crown pattern baldness^[2]. The exact prevalence of PCOS is not known as the syndrome is not defined 52 precisely. The estimated prevalence is 5-10% among the reproductive age women^[3]. PCO receives more attention because of its high prevalence and possibly of its reproductive, metabolic and cardiovascular consequences.

17 Environmental and genetic factors have a major role in the development of 44 PCOS^[4]. Obesity, exacerbated by poor dietary choices and physical inactivity, worsens PCOS in susceptible individuals. The role of other environmental modifiers such as infectious agents or toxins is speculative. 17 PCOS may be common in our society owing to evolutionary advantages of the syndrome in ancient times, including smaller family sizes, reduced exposure to childbirth-related mortality, increased muscle mass and greater 44

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Text-Only Report

DECLARATION

I, **Dr.G.Chinthana** solemnly declare that the dissertation title **“EVALUATION OF EFFICACY AND SAFETY OF MYOINOSITOL IN WOMEN WITH POLYCYSTIC OVARIAN SYNDROME TREATED AT A TERTIARY CARE HOSPITAL”** was done by me at Chennai Medical College Hospital and Research Centre, Irungalur ,Trichy, under the supervision and guidance of my professor and head of the department **Dr.K .Vasanthira M.D.,**

This dissertation is submitted to The Tamil Nadu Dr. M.G.R Medical University, towards the partial fulfilment of requirement for the award of M.D. Degree (Branch –VI) in Pharmacology.

Place: Irungalur

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ABBREVIATIONS

1. PCOS -Polycystic Ovarian Syndrome
2. TGL -Triglycerides
3. LDL-CH - Low Density Lipoprotein-Cholesterol
4. HDL-CH - High Density Lipoprotein-Cholesterol
5. VLDL -Very Low Density Lipoprotein
6. GnRH - Gonadotropin Releasing Hormone
7. MI - Myoinositol
8. OCP -Oral Contraceptive Pill
9. E1 -Estrone
10. NIH/NICHD - National Institutes of Health / National Institute of Child Health and Human Disease
11. ESHRE/ ASRM -European Society for Human Reproduction and Embryology/American Society for Reproductive Medicine
12. USG - Ultrasonogram
13. BMI - Body Mass Index
14. HOMA-IR - Homeostatic Model Assessment Index- Insulin Resistance
15. IGF-1 - Insulin like Growth Factor-1
16. OCT1 & 2 -Organic Cation Transporter 1 & 2
17. DCI - D-Chiro Inositol
18. IRS -Insulin Receptor Substrate
19. GLUT-4 - Glucose Transporter-4
20. ICSI - Intra Cytoplasmic Sperm Insemination
21. FBS - Fasting Blood Sugar
22. IVF - In Vitro Fertilization
23. SHBG - Sex Hormone Binding Globulin
24. NAC - N-Acetyl Cysteine
25. ROS - Reactive Oxygen Species (ROS)
26. CLIA - Chemiluminescence Immunoassay
27. ELISA - Enzyme-Linked Immunosorbent Assay
28. CHOD/POD -Cholesterol Oxidase/Peroxidase
29. PPBS - Postprandial Blood Sugar
30. LH - Luteinizing Hormone
31. FSH - Follicle Stimulating Hormone
32. TSH - Thyroid Stimulating Hormone
33. DHEA-S - Dehydroepiandrosterone-Sulfate
34. TC -Total Cholesterol

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INTRODUCTION

Polycystic ovarian syndrome (PCOS) or Stein - Leventhal syndrome is one of the most common endocrine disorders, affecting 20% of women in reproductive age^[1]. It is a complex multidimensional disorder with presence of polycystic ovaries in a woman with a cluster of symptoms which includes amenorrhoea, oligomenorrhoea, hirsutism, anovulation and other signs of androgen excess such as acne and crown pattern baldness^[2]. The exact prevalence of PCOS is not known as the syndrome is not defined precisely. The estimated prevalence is 5-10% among the reproductive age women^[3]. PCOS receives more attention because of its high prevalence and possibly of its reproductive, metabolic and cardiovascular consequences.

Environmental and genetic factors have a major role in the development of PCOS^[2]. Obesity, exacerbated by poor dietary choices and physical inactivity, worsens PCOS in susceptible individuals. The role of other environmental modifiers such as infectious agents or toxins is speculative. PCOS may be common in our society owing to evolutionary advantages of the syndrome in ancient times, including smaller family sizes, reduced exposure to childbirth-related mortality, increased muscle mass and greater capacity to store energy^[4]. Genetic sequence plays a strong role in the etiology of PCOS^[5]. That is, it is inherited as a complex genetic trait. It is possible that a gene (CYP11A1, CYP17A1) may render the ovary susceptible to insulin stimulation of androgen secretion while blocking follicular maturation^[6].

PCOS develops due to excessive luteinizing hormones (LH) by the anterior pituitary gland with increase in LH/Follicle stimulating hormone (FSH) ratio and through

high levels of insulin in blood and insulin resistance^[2]. The main underlying cause of female infertility is PCOS. The most common immediate symptoms are anovulation, oligomenorrhea, amenorrhea and ultrasound evidence of polycystic ovaries, excess androgenic hormones producing hirsutism, acne, alopecia, seborrhoea and insulin resistance. Certain mood disorders such as sadness, nervousness, bipolar disorder and consumption disorder can happen more habitually in women having PCOS^[7].

Though the diagnostic criterion of PCOS were offered by 3 groups, the ultimate diagnostic criteria for PCOS was based on revised 2003 Rotterdam's Criteria, (2 out of 3 should be positive), a. Oligo ovulation and/or anovulation, b. Excess androgen activity (Clinical or biochemical signs of hyperandrogenism), c. Polycystic ovaries on ultrasonogram, after excluding other causes like congenital adrenal hyperplasia, cushings syndrome, hyperprolactinemia, thyroid disease, acromegaly and androgen secreting tumours of the ovary^[8].

Complications of PCOS include reproductive complications such as increased incidence of miscarriage, endometrial cancer, infertility and cardiovascular complications such as coronary artery disease, hypertension and metabolic complications of obesity, insulin resistance, and type 2 diabetes^[2]. Identification of patients worry is necessary when prioritizing goals and formulating a treatment plan. So the treatment depends on patients requirements of either hormonal contraception or ovulation induction. Lifestyle modification such as behavioral pattern, diet and exercise stays the first line of management. Medications used in the management of PCOS include oral contraceptive agents like ethinyl estradiol, medroxyprogesterone to restore menstrual cyclicality, GnRH

agonists; antiandrogens such as spironolactone, finasteride, flutamide, dexamethazone, selective oestrogen receptor modulator, clomiphene citrate for ovulation induction; hypoglycemic agents such as metformin, thiazolidinediones, topical eflornithine hydrochloride for hirsutism. Surgical management includes electrocautery, laser ovarian drilling and multiple biopsy^[9].

Though the insulin sensitizer-metformin in PCOS has improved metabolic disorders as a consequence of insulin resistance and the subsequent chronic sequelae, such as dyslipidemia, diabetes, hypertension and cardiovascular disease and it is associated with gastrointestinal side effects such as nausea, vomiting, diarrhea, lactic acidosis rarely ^[10]. Another drug, thiazolidinediones are associated with weight gain, cardiovascular events, fragile fractures and bladder cancer^[11].

Recently, Myoinositol (MI) - a novel insulin sensitizer has been developed for treating PCOS with infertility. MI could be proposed as a substitute to metformin treatment because the former can affect insulin target tissues and cells and augment the insulin effects without the side effect of metformin. Certain studies have demonstrated that, treatment with MI is effective in reducing hormonal, metabolic and oxidative abnormalities in PCOS patients by improving insulin resistance^[12]. The need for doing this study of demonstrating the efficacy and safety of myoinositol was because of its limited studies available in India till now pertaining to supplementation of inositol for PCOS treatment.

AIMS AND OBJECTIVES

Based on the survey of literature, the effect of MI on PCOS, it was understood that limited works were carried out on the anovulatory PCOS and infertility cases. Keeping these in mind it was decided to carry out the study to evaluate the effects of MI on PCOS

The objectives of the present study are

To evaluate the effects of MI on ovulation

To evaluate the hormonal effect of MI on hyperandrogenism

To evaluate the metabolic effects of MI on blood sugar and lipids.

To assess the safety of MI on PCOS patients

REVIEW LITERATURE

Definition and type of PCOS

PCOS is a complex heterogenous disorder characterized by oligo ovulation and/or anovulation with increased androgen activity and polycystic ovaries by gynecological ultrasound^[9].

Types of PCOS include (a) Mild PCOS accounts for 16% with irregularity of cycles, numerous cystic ovaries on USG, a little elevated androgen levels and normal level of insulin. (b) Ovulatory PCOS (16%) with normal cycles, polycystic ovaries on USG, elevated androgen levels with increased insulin (c) Hyperandrogenism and persistent anovulation accounts for 7% with irregular cycles, typical ovaries on ultrasound, elevated androgen levels, increased insulin and potential long-term risks (d) 61% of Severe PCOS with irregular cycles, polycystic ovaries on USG, elevated androgen levels, increased insulin and potential long-term risks^[13].

Prevalence

According to the revised Rotterdams criteria, the prevalence amongst the general female population has increased to 10%^[3]. Global prevalence accounts for 2.2% to 26%, roughly 1 in 15 women worldwide, 36% of Indian women are suffering from PCOS^[14].

History of PCOS

The PCOS was previously called Stein-Leventhal Syndrome after the physicians who first characterized it in the 1935. Stein and Leventhal surgically explored the obese women, who presented with amenorrhea, hirsutism, infertility and bilateral enlarged polycystic ovaries. To invent more about the pathology of ovary, Stein and Leventhal

performed ovarian biopsy by taking out wedges of ovarian tissue. The Pathological examination did not showed much results, but surprisingly women started menstruating on a regular basis after 3-5 months. Surprisingly their first patient became pregnant within the 1st year of the surgery after a long period of married life. Based on the work of these two scientists, a primary defect of the ovary was considered to be responsible for this condition and was referred to as Polycystic Ovarian Disease (PCOD). However subsequently, extensive work has thrown light on the fact that PCOD is no longer a disorder confined to the ovaries, but involves a complex pathophysiology of the various organ systems. Hence, PCOD is now referred to as Polycystic Ovarian Syndrome (PCOS)^[15].

Etiology

Genetic sequences has the strong implication in the etiology of PCOS^[5]. Clustering of PCOS in families strongly suggest that mode of inheritance is consistent with autosomal dominant pattern^[2]. It is possible that the gene (CYP11A1, CYP17A1) may render the ovary liable to stimulation of insulin by androgen secretion and thereby leading to blockage of follicular maturation^[6]. Though the genes were grouped in to four categories such as insulin resistance-related genes, genes that interfering with synthesis and action of androgens, gene that codes for inflammatory cytokines and candidate genes, it is the candidate gene which are most likely to be involved in the pathogenesis of PCOS^[9].

Pathophysiology

In a normal state, there will be pulsatile release of gonadotropin-releasing hormone (GnRH) from the hypothalamus. The pituitary gland responds to GnRH by releasing LH and FSH. The FSH and LH stimulate follicle growth. LH enhances ovarian theca cells to release androgens (androstenedione) and FSH stimulates cells of granulosa to change the androstenedione into estrone and estradiol. Both oestrogen and progesterone offer negative feedback to GnRH secreted by hypothalamus and on the pituitary. Several follicles begin to grow with each cycle but only one matures. Estradiol triggers the acute release of luteinizing hormone (LH). LH surge occurs and the mature follicle ruptures^[16].

While in case of PCOS, the follicular growth seems to be normal up to the mid-antral phase, after that the maturation ceases and follicle undergo atresia. The follicular fluid accumulates and follicle got enlarged, the granulosa cell layer degenerates, appears like a thin-walled cyst^[17]. The causative of hyperandrogenism and anovulation in PCOS arises from abnormalities in 4 endocrinologically active compartments such as ovaries, adrenal glands, periphery -which includes fat and hypothalamo-pituitary compartment.

Ovarian compartment was the most reliable contributor of androgen^[9]. The improved ovarian androgen production seen in PCOS was a result of sequence of complex biochemical processes which begins with disordered activity of the enzyme cytochrome P450, 17 α which catalyses 17-hydroxylase and 17/20 lyase activities,^[18] which is the rate limiting step in androgen biosynthesis^[19]. The increased testosterone levels in PCOS were considered to be ovarian in origin and the total testosterone were

usually between 20-80ng/dl. Treatment with GnRH agonist therapy more effectively suppresses serum testosterone and androstenedione levels. Though the hyperfunctioning of CYP17 enzyme coexists in ovaries and the adrenals, DHEA-S was raised in above 50 % of patients.

In the peripheral compartment, the presence or absence of hirsutism was determined by the activity of 5α reductase in the skin . Peripheral aromatization is increased with increased body weight. Oestrogen metabolism got decreased. Estrone (E1) levels are increased as a result of peripheral aromatization of androstenedione^[9].

In hypothalamic-pituitary compartment-PCOS develops due to excessive LH by anterior pituitary gland as a result of pulse frequency of GnRH with increase in LH/FSH ratio and through high levels of insulin in blood and insulin resistance. Persistently elevated levels of LH will produce more amount of androstenedione by causing increased cytochrome P450 activity. Insulin like Growth Factor (IGF) potentiates the expression of LH receptors and stimulates LH induced androgen production and accumulation of androgens in the ovary^[21]. IGF also acts as an amplifier of action of FSH^[20]. FSH levels are not increased because of the combined effect of increased GnRH pulse frequency and synergistic negative feedback on persistently elevated estrogen levels and normal follicular inhibin^[9].

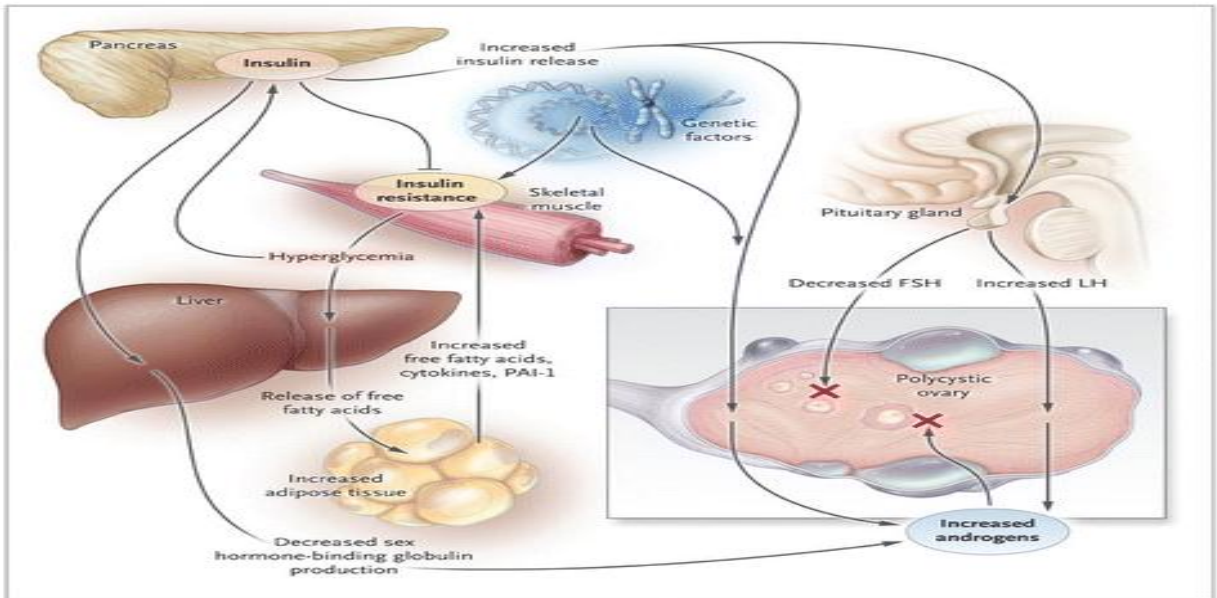


Figure 1. Pathophysiological Characteristics of PCOS

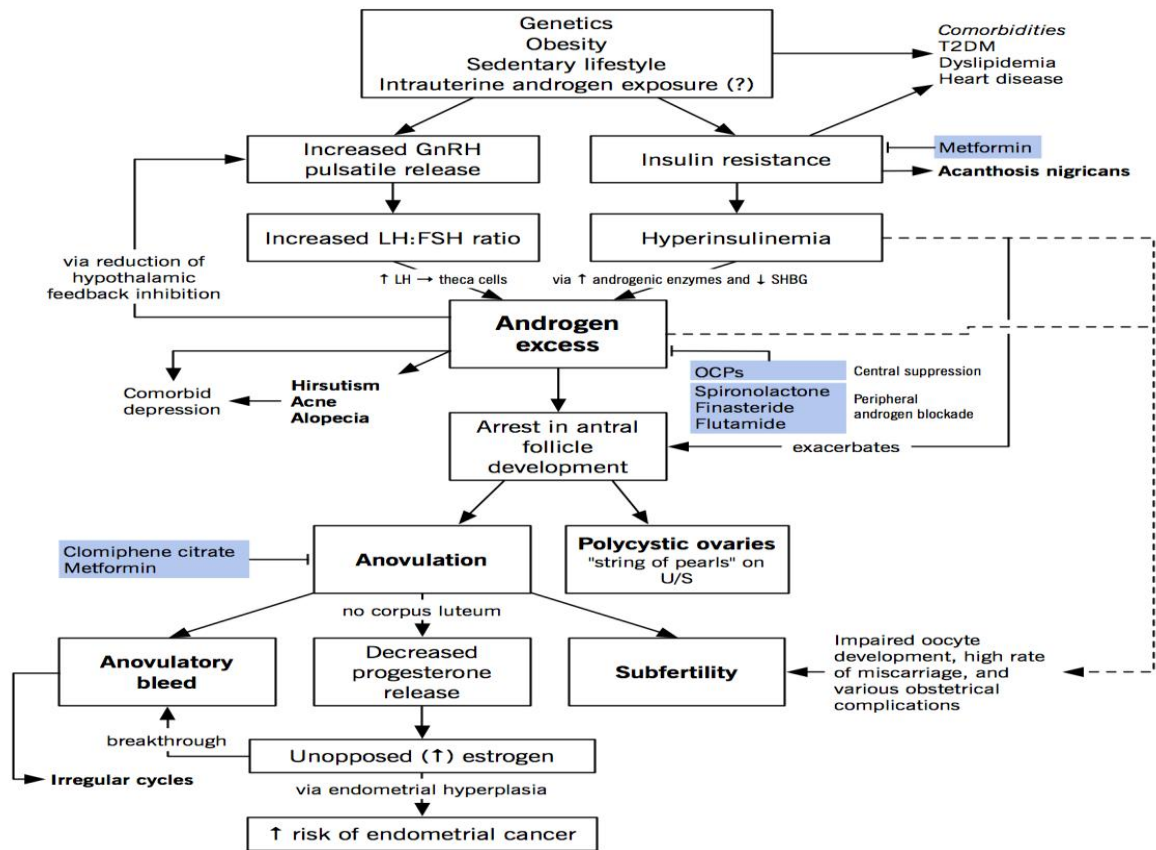


Figure 2. Pathophysiological Characteristics – Flow Chart

Symptoms and diagnostic criteria

The most common symptoms are menstrual disturbances such as oligomenorrhoea or amenorrhoea, and symptoms due to excess androgenic hormones such as hirsutism, acne, alopecia, seborrhea and anovulatory infertility^[7].

The diagnostic criteria for PCOS have been obtained by three groups namely

A. The National Institutes of Health + National Institution of Child wellbeing and Human Disease; based on exclusion of other androgen excess or related disorders include all the following 1. Clinical and/or biochemical hyperandrogenism, 2. Menstrual dysfunction

B. The European Society for Human Reproduction and Embryology/American Society for Reproductive Medicine (ESHRE/ASRM); based on exclusion of other androgen excess or related disorders includes two of the following 1. Clinical and/or biochemical hyperandrogenism, 2. Oligo-ovulation or anovulation, 3. Polycystic ovaries

C. The Androgen Excess and PCOS Society: based on exclusion of other androgen excess or related disorders includes all the following 1. Clinical and/or biochemical hyperandrogenism, 2. Ovarian dysfunction and/or polycystic ovaries^[21].

Recently, the ultimate diagnostic criteria of PCOS is based on the 2003 Rotterdams Criteria, (2 of 3 of the following should be positive). a. Oligo ovulation and/or anovulation, b. clinical and/or biochemical signs of hyperandrogenism, c. Polycystic ovaries on ultrasonogram, after excluding other causes like congenital adrenal hyperplasia, Cushing's syndrome, hyperprolactinemia, thyroid disorder, acromegaly and androgen secreting ovarian tumour^[8].

The menstrual irregularity in PCOS arises from anovulation or oligo ovulation and ranges from amenorrhoea to oligomenorrhoea. Clinical hyperandrogenism includes hirsutism, male pattern alopecia and acne^[9]. But the discrepancy in different states is due to genetically determined differences in 5- α reductase activity^[2]. The sonographic criteria for PCOS required the presence of 12 or more follicles in either of the ovary measuring 2 to 9 mm in diameter and/or increased ovarian volume of more than 10 ml, usually peripherally arranged around an enlarged hyper echogenic central stroma^[9].

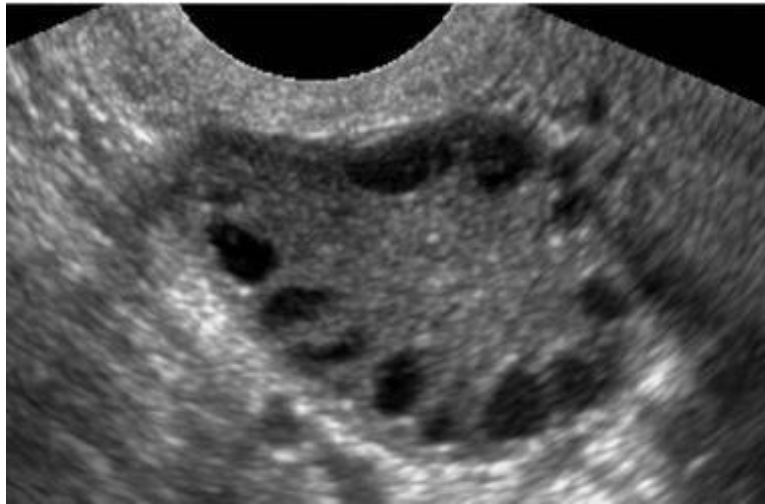


Figure 3. Ultra Sonographic View of PCOS

Association of PCOS with other co-morbidities

Increased incidence of miscarriage, infertility, endometrial cancer and metabolic complications are the common risk factors involved in PCOS. It is associated with central obesity with increased waist-hip ratio leading to increased risk of diabetes mellitus and cardiovascular complications such as coronary artery disease, hypertension^[22,23]. Insulin resistance results in hyperinsulinemia with development of hyperglycemia and type 2

diabetes. Abnormal lipoproteins such as elevated Total Cholesterol(TC), Triglycerides(TGL), Low Density Lipoprotein(LDL) and low levels of High Density Lipoprotein(HDL) were noted^[9]. Women with PCOS has increased prevalence of depression, anxiety and eating disorders^[7].

Management of PCOS

Treatment of PCOS includes non-pharmacological and pharmacological management

Non-pharmacological management

It includes lifestyle modification as the first form of therapy. It includes (a) Gentle or structured exercise for ≥ 30 min /day (b)Dietary changes such as fat \leq 30% per day.(c)Reduced saturated and trans fat and glycemic levels with increased fibre and polyunsaturated fat. Weight reduction is established with an energy deprival of 500-1000 kilo calories/day (d)Reduction of psycho-social stressor, stoppage of smoking, moderate alcohol and caffeine use (e) Group interaction or intervention to support and aid implementing changes^[2,9].

Pharmacological management

Oligomenorrhoea/amenorrhoea with anovulation

(a) Combined Oral contraceptive pill (OCP) – in patients not desirous of conception (b) Cyclic progestins (eg, 10mg medroxyprogesterone acetate for 10 to 14 days every month for 2/3 months) (c) Metformin- to improve ovulation and menstrual cyclicity

Hirsutism

(a) Self-administered and professional cosmetic therapy are the first line (laser recommended) - Electrolysis and photoepilation therapy. If cosmetic therapy is not adequate, pharmacological therapy can be considered (b) Topical Eflornithine cream, (c) Primary therapy is the OCP (d) Anti-androgen monotherapy (eg, spironolactone or cyproterone acetate) -should not be used without adequate contraception (e) Finasteride or flutamide (f) Combination therapy - if 6 months of OCP is ineffective, add anti-androgen to OCP

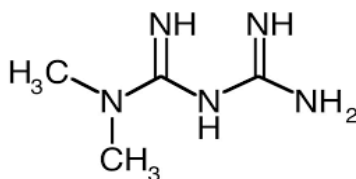
Infertility

Infertility therapies may include clomiphene citrate, metformin, gonadotrophins, surgery (laproscopic ovarian drilling) and in-vitro fertilisation^[6,9].

METFORMIN

Metformin (Biguanide) is an insulin sensitizer widely used for the treatment of patients affected by type 2 DM. As many women with PCOS are insulin resistant, metformin was used in the treatment of PCOS patients also^[24].

STRUCTURE OF METFORMIN



Mechanism of action

Metformin increases the action of AMP-dependent protein kinase. Activated AMPK stimulates fatty acid oxidation, glucose uptake and non-oxidative metabolism and reduces lipogenesis, gluconeogenesis. The net result of these actions is increased glycogen storage in skeletal muscle, lower rates of hepatic glucose production, increased insulin sensitivity and lower blood glucose levels. The drug does not provoke hyperinsulinemia and therefore does not cause hypoglycemia^[25]. In women with PCOS, elevation of circulating insulin and (IGF-I) levels results in overproduction of androgens in ovarian theca cells. Metformin inhibits production of androgens in the theca cells, in part through reducing pituitary secretion of LH, leading to ovulation and regular menstrual cycles^[26].

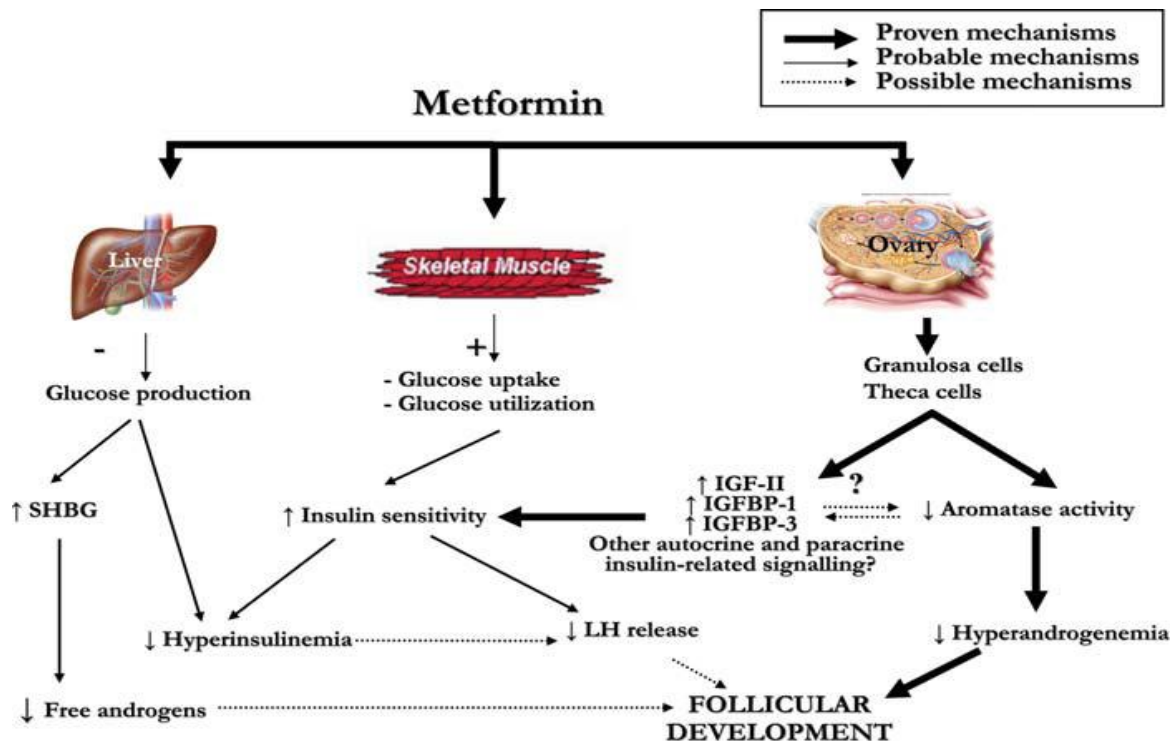


Figure 4. Mechanism of Action of Metformin

Absorption, Distribution & Elimination

The drug is primarily absorbed from small intestine, not bound to plasma proteins, not metabolized and excreted unchanged in urine. Its plasma $t_{1/2}$ is 2 hours, action lasting for 6-8 hours. OCT1 carries the drug in to hepatocytes & myocytes where it is pharmacologically active. OCT2 transports it in to renal tubules for excretion^[25].

Uses

(a).First line therapy for type 2 diabetes (b).Efficacious in preventing the new onset of type 2 diabetes mellitus in middle aged, obese persons with impaired glucose tolerance and fasting hyperglycemia. In combination with insulin secretagogues or thiazolidinediones in type 2 diabetes in whom oral monotherapy is inadequate (c).Decrease the risk of macrovascular as well as microvascular disease (d).Reduces circulating androgens and hirsutism, restores menstrual cyclicality and improves ovulation and fertility in infertile women with polycystic ovary, irrespective of glycemic status of the women^[27].

Adverse Effects

The most common adverse effects are anorexia, nausea, vomiting, abdominal discomfort and diarrhea which are dose related and tend to occur at the onset of therapy and are transient. Absorption of vitamin B12 appears to be reduced on long term metformin therapy. Small increase in blood lactate levels (lactic acidosis) can occur which is rare (<1 per 10000 patient years)^[27].

Contraindication

Metformin is contraindicated in renal disease, hepatic disease, alcoholism or conditions predisposing to anoxia (cardio-pulmonary dysfunction) because of increased risk of lactic acidosis^[27].

DrugInteraction

Dose adjustments of metformin is needed in patients taking cationic medications such as cimetidine, furosemide and nifedipine because it competes with metformin excretion and enhances its toxicity^[25].

Dose

0.5-1 gm twice daily (with the lowest effective dose recommended and titrated over days to weeks to minimize side effects)^[25].

CLINICAL OUTCOMES OF METFORMIN

In a study conducted by Maciel *et al* in 2004, between 29 lean versus obese PCOS patients for a period of 6 months with 500mg of metformin thrice a day (TID), showed that Significant reduction in insulin resistance (fasting insulin), androgen levels (total and free testosterone, androstenedione) among lean PCOS. In obese PCOS, only enhancement of free testosterone levels and all other parameter showed no change^[28].

In a study conducted by Marcondes *et al* in 2007 in 12 normal weight PCOS patients, BMI 21.5 ± 1.65 kg/m² with metformin 850 mg TID for 4months, it showed nil effect of BMI or hirsutism scores, but there were significant improvement of ovulation

rate, testosterone and parameters such as fasting insulin, HOMA-IR as well as decrease of LH and increase in FSH^[29].

In a study conducted by Moghetti P among 23 PCOS patients with metformin 500 mg three times a day or placebo for 6 months, it showed improvement in mean frequency of menstruation ($P = 0.002$) after metformin therapy, due to striking amelioration of menstrual abnormalities in about 50% of subjects. Women given metformin showed reduced plasma insulin ($P < 0.01$) and increased insulin sensitivity ($P < 0.05$). Concurrently, ovarian hyperandrogenism was attenuated, as indicated by significant reductions in serum free testosterone ($P < 0.05$) and in the 17-hydroxyprogesterone response to GnRH-agonist^[30].

In a study conducted by Fleming R in 92 PCOS patients with Placebo or metformin 850 mg, twice a day for 14-weeks Showed that rate of recurrence of ovulation assessed by the fraction of luteal period weeks to observation weeks was notably (P value < 0.01) superior in the treated subjects (23%) in comparison with the placebo (13%), and the time for initial ovulation was notably ($P < 0.05$) shorter. The fraction of patients who failed to ovulate throughout the placebo-treatment was high ($P < 0.05$), and the mass of ovulations are indicated by normal level in both groups. The outcome of metformin on maturation of follicle was quick, because of the E2 concentration were greater over the 1st week of treatment. Notable ($P < 0.01$) for weight reduction was recorded with the metformin group, while the placebo showed increased weight ($P < 0.05$). A significant raise in circulating HDL was noticed only with metformin group. The benefits of metabolic risk with metformin was not observed in obese subgroup ($BMI > 37$). No

alteration in fasting glucose or insulin, or insulin response to glucose challenge was observed after metformin or placebo^[31].

In a systemic review and meta analysis of metformin on PCOS by Jonathan M Lord *et.al* in 2003, showed that metformin is effective in achieving ovulation in women with PCOD, with odds ratios of 3.88 (95% confidence interval 2.25 to 6.69) for metformin compared with placebo. An analysis of pregnancy rates shows a significant treatment effect for metformin and clomiphene (odds ratio 4.40, 1.96 to 9.85). Metformin has an effect in reducing fasting insulin concentrations, blood pressure, and low density lipoprotein cholesterol. We found no evidence of any effect on body mass index or waist: hip ratio. Metformin was associated with a higher incidence of nausea, vomiting, and other gastrointestinal disturbances^[32].

DRAWBACKS OF THE EXISTING MEDICATION

Oestrogen + progesterone: May enhance hazard of thrombo embolic episodes and metabolic risk, gastro-intestinal disturbances(GIT), tenderness of the breast, reduces insulin sensitivity, glucose intolerance, alteration in lipid profiles.

Anti oestrogen (Clomiphene citrate): 20% of patients showed resistance. Associated with higher parity, hot flushes, hyper stimulation of ovary and ocular toxicity. It is reasonably effective as monotherapy, Least effective in obese PCOS, Showed uneven success rate.

Biguanide (Metformin): Accompanied by reduction in blood glucose and raise of serum homocysteine level. It is less effectual for hirsutism. Associated with GIT distress and unpleasant metallic taste. Many drug interactions can occur.

Antiandrogens (Spironolactone): Raised blood levels of potassium, hepatitis, GIT discomfort, irregular menstrual bleeding, abnormality in sexual differentiation of male fetus.

5 α -Reductase inhibitors: Should not be targeted on to the iso enzyme-5 α -reductase in the pilosebaceous unit.

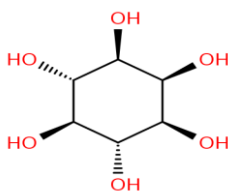
The above available medication has certain disadvantages. The adverse events can limit the outcome of the above medication. The mechanisms to enhance ovulation together with symptom control is the optimal aim in reproductive medicine. Moreover, the drugs must have an excellent safety profile. Hence by keeping these in mind myoinositol appears to be a promising therapy^[33].

MYO-INOSITOL(MI)

Chemistry and source

Inositol, a hexahydroxycyclo-hexane was isolated from the muscle in 1850 by Johannes Joseph Scherer from the Greek word as “sinew, fiber“, a “carbohydrate”, “ester“, an “alcohol”, and it comes under the sugar-family^[34]. The main component in phytates was Inositol that is it exists as crystals of the inositol hexaphosphoric acid(IHP). This phytate was discovered by Hartig in 18th century as small spherical particles from seeds of various plants which resembled in size as starch grains of potato^[35]. These particles were richest source of phosphorous, calcium and magnesium but lacks lipids or proteins.

STRUCTURE OF MYOINOSITOL



Inositol is a chemical compound with formula $C_6H_{12}O_6$, a sixfold alcohol (polyol) of cyclohexane. MI appears to be one of nine stereoisometric of a C6 sugar alcohol that belongs to vitamin B-Complex group^[36,37]. Inositol is a carbohydrate, assayed at half the sweetness of sucrose.^[38] The precursor of inositol triphosphate is MI. The former acts as a 2nd messenger in controlling certain hormones such as Thyroid Stimulating Hormone, Follicle Stimulating Hormone and insulin^[39].

Another study conducted in 1988 stated, MI and D-chiro-inositol(DCI) are the two stereoisomers of inositol^[40], which are chemical mediators of insulin, acting through different mechanisms. Both DCI and MI have identical structures, but differ in the chemistry with one OH group^[41]. The second messengers for FSH and glucose uptake were produced by MI, while the same for improving the uptake of glucose and synthesis of glycogen were provided by DCI^[11,36]. The synthesis of MI from glucose-6-phosphate (G-6-P) occurs by following steps. Initially the isomerisation of (G-6-P) by inositol-3-phosphate synthase enzyme yields myo-inositol 1-phosphate, which undergoes dephosphorylation by an inositol-monophosphatase enzyme (IMPase1) to give free MI^[36].

MI is an essential nutritive component of cell membrane essential for the growth and viability of human cells in the culture^[39]. The serum concentration of MI in healthy

adults remains within a range of 20-70 $\mu\text{mol/L}$, whereas in new-born infants and fetuses, it is several times higher than in adults^[42]. Most inositol is synthesized in the human kidneys, in typical amounts of a few grams per day^[43]. Certain studies were reported that testes, the prostate gland, the epididymis and seminal vesicles contain enormous quantity of MI^[42]. The seminal fluid in male and ovarian fluid in female is the richest sources of inositol. MI is naturally present in plant foods and in high concentration in fruits, beans, grains, and nuts^[11,36,44].

Mechanism of action

MI is a precursor of DCI. DCI is synthesized by an insulin dependent epimerase that converts MI into DCI.

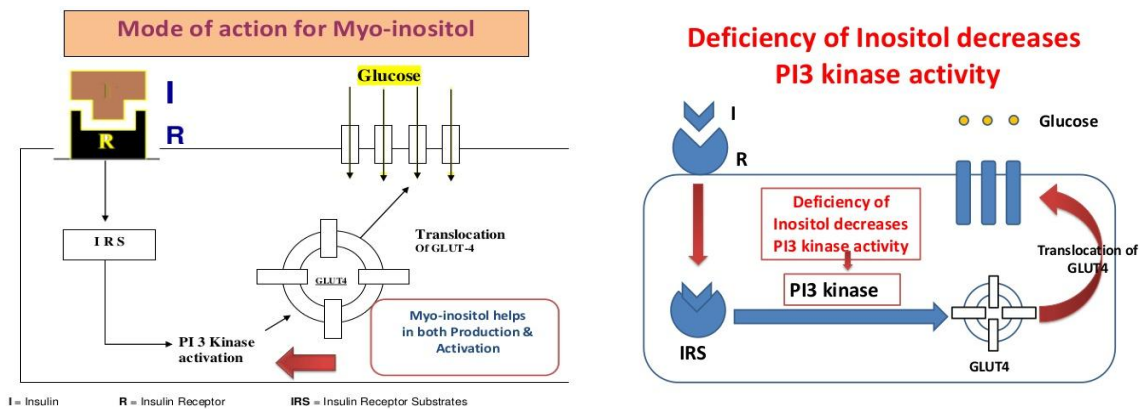


FIGURE 5. Mechanism of Action of Myo-inositol

Insulin binds to its receptor forms a complex called Insulin Receptor Substrate (IRS). IRS Stimulates the messenger called PI3 kinase. MI helps in both production and activation of PI3⁽³⁴⁾. Activated PI3 kinase activates GLUT4. Glucose is then taken up by

GLUT4 through glucose channel for utilizing energy. Then IRS Complex breaks down releasing the receptor to go back to its original site^[45].

Uses

MI has been implicated in insulin signal transduction^[46, 47] and found to be effective in treatment of insulin resistance, hyperandrogenism, and oligo-amenorrhea in PCOS^[35,36]. MI also improves features of dysmetabolic syndrome in post-menopausal women, including (TGL), HDL cholesterol and diastolic blood pressure^[48]. MI is also used in panic disorder, Obsessive Compulsive Disorder, unipolar and bipolar depression, acute respiratory distress syndrome in premature infants and lithium induced psoriasis but occasionally cause nausea, tiredness, headache, dizziness. Inositol can boost the effects of selective serotonin reuptake inhibitors^[49].

Dose, Administration, Duration

Dose is 200- 4000 mg once a day before breakfast for PCOS. MI is available in two types of dosage form one in powder form and another newer pharmaceutical preparation -soft gelatin capsule. A study on administration of MI as powder and soft gelatin capsules resulted in a different bioavailability. MI in Soft gelatin capsule form showed similar pharmacokinetic parameters compared with three times higher doses of MI in powder form^[50]. There were certain clinical studies which showed the relationship between augmentation of the insulin tissue sensitivity and DCI or MI oral supplementation for three months^[51].

CLINICAL OUTCOMES OF MI

Effect of MI on Infertility/Ovulation and Oocyte quality

Many studies stated that MI improves oocyte and embryo quality of PCOS. The prevalence of infertility among anovulatory PCOS women varies between 35-94%^[52]. Supplementation of MI on PCOS patients with oligo-ovulation, high testosterone, hirsutism cases, improves ovarian function, metabolic and hormonal parameters^[8,48]. Another study on PCOS women with MI and placebo showed that, 69.5% ovulated in MI group compared to 21% in placebo. A study on calcium signaling in oocytes in various species depicts the inositols putative role in oocyte maturation and the early stages of fertilization^[53,54,55] and quality of the oocytes^[36]. The presence of MI in high levels indicate the well being of the follicle. In a prospective randomized comparative study performed between MI and DCI showed, improvement of the oocyte and embryo quality in MI than DCI in PCOS^[56]. In another study, though MI and/or DCI administration improves insulin sensitivity only MI is a quality marker for oocytes evaluation^[57]. In a randomized control open label study conducted on patients undergoing Intra Cytoplasmic Sperm Insemination(ICSI) or with prior failed attempts of ICSI showed MI improved oocyte quality in PCOS patients compared to folic acid alone^[58]. Another study showed that, insulin lowering medications, particularly different isoforms of inositol, when administered to patients undergoing ovulation induction for ICSI represent novel therapies for restoring spontaneous ovulation, with a potential positive effect on human oocyte meiotic maturation^[59]. Randomized controlled trials of MI in women with PCOS

showed improvement in ovarian function and metabolic and hormonal parameters in women with PCOS^[60].

Many ovulatory cycles in PCOS women are accompanied by elevated Estrone (E2) and subnormal Plasma concentrations, indicating a suboptimal follicular maturation and ovulation with a collection of high number of germinated vesicles and oocytes with degeneration during ovum pick-up^[59]. In a 14 weeks study performed to determine the efficacy of inositol on ovarian and metabolic factors in PCOS showed increased ovulation frequency defined by luteal ratio, with increase in ovulation rate evidenced by raise in E2 concentrations in MI group through the 1st week of medication and shorter mean time to first ovulation^[61]. A study on association between MI concentration with follicular volume and E2 level, showed that there is better development of the oocytes with higher level of MI in ovarian follicular fluid depicting the wellbeing of the follicle and the quality of oocyte^[62]. A study on chronic anovulatory infertility in PCOS undergoing assisted reproduction techniques showed number of follicles with a diameter of more than fifteen millimeter visible at abdominal scan during stimulation protocol and significantly more number of oocytes were retrieved at the pickup in MI group^[48].

In another prospective comparative study on the efficacy of a treatment with MI + folic acid + melatonin with MI + folic acid alone on PCOS women who underwent In Vitro Fertilization(IVF) cycles showed that the beneficial efficacy of MI + folic acid in improving fertility rate and the coadministration of melatonin can improve the quality of oocyte and the outcome of pregnancy in women with history of meager oocyte

quality^[36]. Hence it was anticipated recently as a preventor of folate resistant neural tube defects^[43].

Melatonin is present in both male and female reproductive system. The increased level of melatonin in the ovarian follicular fluid and seminal fluid is responsible for the reproductive function. It is an antioxidant and free radical scavenger that protects follicles from oxidative stress, rescuing them from atresia, leading to complete follicular maturation and ovulation. The human seminal fluid contains melatonin, and it stimulates flagellar motility of spermatozoa where spermatozoa express melatonin receptors. Hence there exists a direct correlation between melatonin concentrations in follicular fluid and oocyte quality^[63,64].

The concentration of MI and DCI in the follicular fluid of PCOS patients verses healthy subjects, showed that follicular fluid from regular cycles of healthy patients contains elevated concentrations of MI with low concentrations of DCI while in PCOS cases, the ratio of the above molecules were entirely opposite. These reports were in favour of the “DCI paradox”, accordingly to which “ovaries of PCOS individuals were liable to present an increased MI to DCI epimerization which lead to tissue diminution of MI that could finally be accountable for the poor oocyte quality in these patients. Further, increasing DCI dosage progressively worsens oocyte quality and ovarian response^[65,66]. A study conducted by Isabella, depicted that rising doses of DCI showed “ovary toxicity”, characterized by a harmful impact on oocyte quality, and a progressive decline in the ovarian response to FSH^[36].

PCOS have irregular menstruation pattern ascribed to persistent anovulation. The menstrual irregularities in PCOS usually manifest around the time of menarche^[67]. Some PCOS women have oligomenorrhea or secondary amenorrhea. Scanty menstruation has been noticed in 85-90% of PCOS women and 30-40% of amenorrheic patients have PCOS. Anovulatory menstrual cycles may lead on to dysfunctional uterine bleeding and infertility.

Several prospective randomized controlled studies have stated that MI capable of restoring spontaneous ovarian activity with consequent fertility^[59] and improves ovulatory function^[59,68,69]. A Study on PCOS less than 35years showed, though both metformin and MI can be considered as first line treatment for restoring normal menstrual cycles, MI treatment seems to be more effective than metformin^[70].

MI and Pregnancy

In general, PCOS patients are subfertile because of ovulatory disorders and often need ovulation induction drugs, such as clomiphene citrate or FSH, which can increase the risk of multiple pregnancy and ovarian hyperstimulation syndrome. In a study conducted by papaleo *et.al*, Myo-inositol is capable of restoring spontaneous ovarian activity and consequent fertility in most patients with PCOS and the treatment with MI did not cause multiple pregnancy^[69].

A 2-year, prospective, randomized, open-label, placebo-controlled study was carried out in pregnant women having family history of type 2 diabetes who were treated with MI 2g plus folic acid 200µg twice a day may reduce the incidence of Gestational Diabetes Mellitus and the delivery of macrosomic fetuses^[71].

MI and Insulin resistance

Several studies have reported that insulin resistance is common among PCOS women, regardless of the body mass index^[60]. The prevalence of insulin resistance in PCOS ranges from 50%–70% and occurs independently of obesity and the effect of obesity on insulin resistance is additive to that of PCOS^[72,73]. MI increases whole body insulin sensitivity index^[53]. A 12weeks study on PCOS showed improved glucose to insulin ratio and Homeostatic Model Assessment (HOMA) index, decreased serum free testosterone concentration, Dehydroepiandrosterone-Sulfate(DHEA-S), increased Sex hormone-binding globulin(SHBG)^[53,68,74] and reduced LH/ FSH ratio^[74]. According to the study performed for treatment of cutaneous disorders in young PCOS women for 3 months “the administration of MI is a simple and safe treatment that ameliorates the metabolic profile of PCOS patients and reducing hirsutism and acne^[75] through its actions of decreased testosterone and insulin levels, the participants who supplemented with MI experienced a reduction in hirsutism, and improvements in skin appearance. A 12 weeks study with MI 2 grams + folic acid 200 mcg showed improved insulin sensitivity and androgen levels^[76] with loss of weight^[60]. In a study conducted for 6-8 weeks on insulin resistant PCOS women showed oral administration of DCI would improve insulin sensitivity^[68].

The N-acetyl-cysteine(NAC) - a newer mucolytic remedy performing as insulin sensitizer, reflects an successful and harmless approach in the management of PCOS. It exerts its favorable outcome together by raising the insulin secretion from the beta cells of the pancreas and by enhancing an improved sensitivity to the person. Based on

evaluating the efficacy of NAC + Inositol + folic acid on ovulation rate and menstrual regularity in PCOS patients with and without insulin resistance states that MI and NAC may have supplementary non- insulin related action that allowed profit also in those individuals with “-ve” HOMA-index^[77].

A study conducted for 12 weeks showed administration of MI on obese PCOS with micro polycystic ovaries at USG showed reduction in LH, prolactin, insulin levels and LH/FSH ratio, improved insulin sensitivity results and menstrual cyclicity restored^[76].

MI on Obesity

Obesity is common in PCOS women. Nearly 30% to 60% of PCOS women presents with obesity^[33]. Obesity is a common risk factor of developing PCOS and metabolic dysfunction like insulin resistance^[2]. Obesity exacerbates the medical and marker of atherosclerosis namely endothelial functional impairment, impaired pulse wave velocity, enlarged carotid intima media wall depth, occurrence of carotid plaque and amplified coronary artery calcification observed in PCOS women^[78]. MI reduces plasma TGL, TC^[53,68], LDL cholesterol and increased HDL cholesterol as observed from previous studies. As per Women ischemia Evaluation Study(WISE), the greater number of cardiovascular events were noted in PCOS. A study performed for 6 months with MI plus D-chiro-inositol combined therapy further improves the metabolic profile of PCOS women by significantly reducing the total cholesterol, LDL, TGL, fasting insulin, fasting glucose and HOMA index and increased HDL level, thereby reducing the cardiovascular risk^[78] and weight loss in MI group by reducing circulating leptin level. In another

randomized controlled trial, combining MI and DCI more effectively reduces the metabolic risk in overweight PCOS in comparison to MI supplementation alone, after three months of treatment^[79]. In a 6-8 weeks study Systolic and diastolic blood pressure has been reduced in MI treated PCOS women^[53,68].

The success of different artificial reproductive techniques depends on Reactive oxygen species (ROS) which are produced within the follicle during the ovulatory process, and it is believed that oxidative stress may be a cause of poor quality of oocytes, pathogenesis and future complications of PCOS. High levels of oxidants, such as H₂O₂, has been found in fragmented embryos^[80]. The intermediaries namely the ROS of a standard oxygen metabolism were produced quicker than the endogenous antioxidant defense systems can neutralize. The inter and/or intra molecular cross-linking, inducing protein degradation, clustering, and enzyme inactivation occurs due to oxidation. A study on MI administration decreases the oxidative stress in erythrocytes of PCOD individuals. Certain previous studies have demonstrated that hyperglycemia increases ROS generation from peripheral blood leukocytes. The resulting oxidative stress may contribute to a pro-inflammatory state which induces IR and hyperandrogenism in women with this disorder and also increases the risk of cardiovascular events^[12].

Safety of MI

As Several previous studies performed for 1 month suggested that MI is a safe and effective drug, the safety profile from MI reported that mild side effects of nausea, flatus and mild insomnia occurred at doses of 12 grams/day or higher. The dosage

commonly used in clinics, that is 4 g/day of inositol is completely free of side effects^[43]. A study on pharmacokinetics and safety of a single intravenous dose of MI in preterm infants suggest that supplementation of inositol is safe and beneficial for preterm infants with respiratory distress and there is no evidence for MI drug interaction so far^[81].

A study on pharmacokinetics of inositol stated that phosphates of inositol were produced from the initial inositol molecule, with every day dietetic intake of inositol of 1 gm. On reaching the intestinal cells, inositol gets phosphorylated to IHP and undergoes dephosphorylation to (IP1-5), which is responsible for signal transduction. MI was proposed to be absorbed immediately, elated intracellular and dephosphorylated to lower phosphates and it can reach the tumour tissue soon after administration^[33].

In human trials for chemoprevention of lung cancer, states that agents that affect the PI3K/AKT/mTOR pathway act as potential chemotherapeutic agents. Evidence shows that metformin and derivatives of MI also inhibits PI3K/AKT/mTOR signaling pathway particularly in lung-cancer cell lines. Further the regression of dysplasia correlates with decreased PI3K activity in patients who had received MI. The efficacy of inositol is further increased by combining with budesonide, dexamethasone, NAC and indole 3 carbinol. In several studies, oral inositol inhibited lung tumorigenesis in mice exposed to carcinogen^[82].

There were certain known fact that patients with increased levels of insulin need more number of FSH IU while undergoing ovarian stimulation protocols. MI deficient ovary would impair the FSH signaling, resulting in an increased risk of ovarian hyperstimulation in PCOS patients. The physiological ratio of the two isomers (MI/DCI)

as 40:1 appears to be the best approach for the PCOS treatment. In order to ensure the proper dose and clinical efficacy without compromising ovarian function, manufacturing the product as soft gel capsules, by decreasing the dosage to a 3rd of the original powder-based drug has been employed. From the above inventive formulation scientists anticipated to obtain a two-fold effect: (1) DCI- acts on liver, aimed at reducing insulin levels in blood; (2) MI- specific action on the ovary, to counteract the increased DCI levels and reestablishing the FSH sensitivity^[36]. Development of soft gelatin capsules is of growing interest and several studies have reported the ability to perform a uniform, faster and enhanced absorption compared to other oral forms^[83,84].

MATERIALS AND METHODS

Study centre

The study was conducted after obtaining institutional ethical clearance from institutional ethical committee (IEC), Research cell of Chennai Medical College Hospital and Research Centre (Affiliated to the Tamil Nadu Dr.MGR Medical University), Irungalur, Tiruchirappalli

Study Period

24 weeks (from November 2015 to April 2016).

Chemicals

Drugs used in this study were Metformin 500mg twice a day, Myoinositol 2gm twice a day

Inclusion Criteria

PCOS selected according to Rotterdam's criteria in the age group of 18-40 years were included in this study

Exclusion Criteria

Patients on hormonal treatment for infertility in last 6 months, patient with increased risk of lactic acidosis, diabetic patients on insulin and insulin sensitizers, pregnancy and lactation, liver failure, renal failure, lung diseases, ischaemic heart disease and peripheral vascular disease were excluded from the study

Methodology

The present study was a prospective, open labelled, parallel arm, randomized control study to evaluate the efficacy and safety of Metformin versus MI in women with PCOS during the study period of 24 weeks. Total of 132 patients were screened according to Rotterdams criteria, out of which 90 PCOS patients who fulfilled the inclusion and exclusion criterias were recruited for this study after obtaining informed consent from the patients. The selected study subjects were randomly divided in to three groups of 30 each. Subjects in each group was treated as follows and continued without any change in the treatment for the entire duration of the study.

Group	No of subjects	Subject descriptions
1	30	Control -PCOS patient who delays specific treatment but follows Non-Pharmacological treatment
2	30	PCOS subjects + Tab. Metformin 500mg twice a day
3	30	PCOS subjects + Tab. Myoinositol 2gm twice a day

Clinical Assessment:

All the subjects were interviewed regarding age, past history, personal history, family history, menstrual history, obstetric history, treatment history before starting the study. Height, weight, BMI, abdominal circumference, blood pressure and ultrasonogram(USG) were assessed for all the patient at baseline and periodically during the study period. Patients were advised to follow regular exercise and life style modifications during the study period

Biochemical analysis:

About 5ml of blood was collected in the morning hours after a 12-hours fast and a 30-minutes of rest in the supine position. Blood was added with an appropriate anticoagulant before estimation. Blood samples were obtained during the early proliferative phase (second through third day). Biochemical parameters such as LH, FSH, TSH, Prolactin, Fasting serum insulin, Serum-Total Testosterone & Free Testosterone, Dehydroepiandrosterone-sulfate(DHEA-S), Serum Androstenediones, (Metabolic)- TC, TGL, LDL and HDL, Fasting blood Sugar (FBS) were evaluated at baseline, 4th week, 8th week and 12th week , 16th week, 20th week, 24th week of the study period.

BLOOD SUGAR

Blood Sugar-Fasting (FBS)

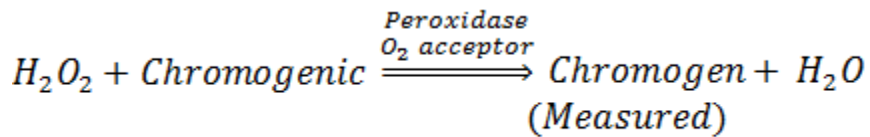
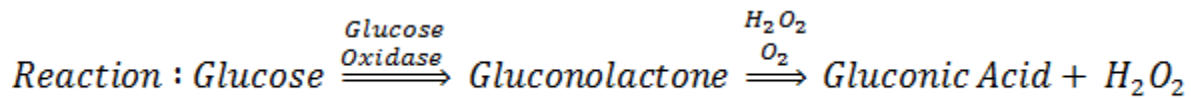
The sample of blood was collected after the patient fasts for twelve hours /overnight.

Blood Sugar - Post-Prandial (PPBS)

After 12 hours of fasting, a meal containing starch and sugar (approx. 100 gms) were given. Blood was collected two, hours after the ingestion of the meal.

Glucose Oxidase Method:

Glucose oxidase catalyses the oxidation of glucose to gluconic acid and hydrogen peroxide. This H₂ O₂ is broken down to water and oxygen by a peroxidase in the presence of an oxygen acceptor which itself is converted to a coloured compound, the amount of which can be measured colorimetrically. This method is used in various autoanalyzers.



FASTING INSULIN

The principle followed a solid phase two site immunoassay. Make the preferred number of layered well in the possessor. Fifty μl of standard sample of insulin, specimens, and control are dispensed to the proper wells. Thoroughly mix it for ten sec. Hundred μl of Conjugate are dispensed into every well. The contents were assorted completely for thirty second. It was placed at room heat for 60 minutes. The microtiter plate was washed and emptied five times with wash solution (300 μl each well). Hit the microtiter platter onto absorbent material to eliminate all remaining droplets of H_2O . 100 μl - Chemiluminescence substrate was dispensed in every well. It was lightly mixed for ten sec. The effect was stopped by addition 100 μl Stop liquid to each well. Then mixed for ten second till the blue colour got entirely changed to yellow colour. The visual density was read at 450 nm with micro plate reader in fifteen minutes.

HORMONAL PROFILE

LUTEINIZING HORMONE (LH)

The principle of this immunoassay followed a classic 2-step 'sandwich' kind of assay. Specimen Pretreatment was not needed. The reagents were kept at room warmth before use. The assay of Calibrator, control sample and specimen were made in replication. The effective solutions of the anti-h LH-HRP and rinse buffer were prepared. The essential amount of micro wells strips was removed. Twenty five microlitre of each of the above assay samples were pipetted to concomitantly labeled wells in replica

100 microlit of test buffer was pipetted into each well (multichannel pipette was recommended). Then incubated on a plate shaker (approximately 200 rpm) for 30 minutes at room temperature. The wells were washed thrice with 300 μ l of diluted wash buffer per well and the plate was tapped firmly against absorbent paper to ensure that it was dry (washer is recommended). 100 μ l of the conjugate working solution was pipetted into each well. Incubated on a plate shaker (approximately 200 rpm) for 30 minutes at room temperature. The wells were washed again in the same manner. Hundred microlitre of TMB was pipetted in every well at same time intervals. Then incubated on a plate mixer for fifteen min till the calibrator showed dark blue colour for required OD. Fifty μ litre of stop solution was pipetted to all well at the similar timed intervals. The plate was read on a microwell plate reader at 450 nm within 20 minutes after addition of the stop solution.

FOLLICLE STIMULATING HORMONE (FSH)

The FSH (Human) CLIA Kit was based on the principle of a solid phase enzyme-linked immunosorbent assay. The desired number of coated well was secured in the holder. The data sheet was made with sample identification. 50 µl of FSH standard, samples, and controls were dispensed into appropriate wells. 100 µl of Enzyme Conjugate Reagent was dispensed into each well. Then mixed thoroughly for 30 seconds. Incubated at room temperature (18-25°C) for 60 minutes. The incubation mixture was removed by flicking plate contents into a waste container. The microtiter wells were rinsed and flicked 5 times with washing buffer. The wells were sharply struck onto absorbent paper to remove residual water droplets. 100 µl Chemiluminescence substrate solution was dispensed into each well. Then mixed gently for 5 seconds. The wells were read with a chemiluminescence microwell reader 5 minutes later.

THYROID STIMULATING HORMONE (TSH)

The TSH (Human) CLIA kit test utilizes a unique monoclonal antibody directed against a distinct antigenic determinant on the intact TSH molecule. The preferred numeral of layered well was held in the receptacle. 50 microlitre of normal standard, samples, and control were dispensed into suitable wells. 100 µlit of Enzyme Conjugate were immersed into all well. Then mix it for thirty seconds. Incubate at room temperature (18-22°C) for about 60 minutes. Rinse and flick the microtiter wells 4 times with washing solution and final 1 time with distilled water. The wells were sharply struck onto absorbent paper to remove residual water droplets. 100 µl Chemiluminescence substrate solution was dispensed into each well. Mixed gently for 5

seconds. The wells were read with a chemiluminescence microwell reader after 5 minutes.

PROLACTIN

The prolactin testing was a chemiluminescence immunoassay, based on the sandwich principle. The desired number of Microtiter wells in the frame holder was secured. 25 μL of each Standard, Control and samples were dispensed with new disposable tips into appropriate wells. Dispense 100 μL Enzyme Conjugate into each well. Mixed completely for 10 seconds. Incubated for 30 minutes at room temperature. The contents of the wells were shaken briskly. The wells were rinsed 5 times with diluted Wash Solution (400 μL per well) and the wells were sharply stiked on absorbent paper to remove residual droplets. Then 50 μL of the freshly prepared Substrate Solution was added to each well and incubated for 10 minutes at room temperature. Read the RLU with a microtiter plate luminometer within 20 minutes after incubation time of substrate.

SERUM TESTOSTERONE

The principle of the following enzyme immunoassay test followed the typical competitive binding schematic. Specimen Pretreatment not required. The reagents ought to be in normal heat prior to usage. The assay of the calibrator, controls and specimen were made in replica. The effective preparation of the testosterone-HRP and rinsing solutions were made. The necessary quantum of the micro strips was detached. Then it was resealed and any idle strips were returned to the fridge. Fifty μL of every calibrator, run and specimen test were pipetted into equally labeled wells in replica. Then Pipette it out 100 micro litre of the conjugate solution into the wells. Incubated on a plate

rotator(200 rotations) for one hr. The wells were washed thrice with three hundred μ litre of watery rinse buffer in well and strike the platter hardly onto permeable paper to make sure that it was dried out Then pipette one fifty μ lit of substrate to each well at specific intervals and incubate on a plate rotator for ten -15 minutes at normal temperature .50 micro litre of stop liquid was pipetted out into all well at the same intervals. Following adding up of stop solution, the platter on a micro well reader was read at 450 nanometer in twenty minutes

ANDROSTENEDIONE

Since it is necessary to perform the determination in duplicate, two wells for each of the six points of the standard curve (S0-S5), two for each sample, one for Blank was prepared.

Reagent	Standard	Sample	Blank
Sample		25 μ L	
Standard S0-S5	25 μ L		
Control	25 μ L		
Conjugate	100 μ L	100 μ L	

Incubated at 37°C for 1 hour

The contents from each well were removed. The wells were washed 3 times with 300 μ L of diluted wash solution. Repeat the washing procedure by draining the water completely

Substrate	100 μ L	100 μ L	100 μ L
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Incubate at room temperature 22-28°C for 15 minutes in the dark.

TOTAL CHOLESTEROL (TC)

Specimen: Serum

Pipette into Dry test tubes	B	S	T
Cholesterol Standard (R ₁)	1 ml	1 ml	1 ml
Cholesterol Standard (R ₃)	-	0.01 ml	-
Serum	-	-	0.01 ml

Mixed well and kept in the room temperature for 10 min. The absorbance of standard and sample was read against reagent blank at 505 nm on spectrophotometer GS5701V within 60 minutes.

$$\text{Cholesterol (mg/dl)} = \frac{\text{Absorbance of Test}}{\text{Absorbance of Std}} \times 200$$

HDL – CHOLESTEROL

Specimen – Serum

Assay

	Pipette into centrifuge tube	Qty
Step I	Serum	0.2 ml
	Precipitating Reagent (R ₂)	0.2 ml

Mixed well and kept at room temperature for 10 min.

Measured the absorbance of standard and sample against reagent Blank at 505 nm on spectrophotometer GS5701V (Electronic Corporation of India Ltd.) within 60 minutes.

Calculations

$$HDL - Cholestrol \left(\frac{mg}{dl} \right) = \frac{Absorbance \ of \ Test}{Absorbance \ of \ Std} \times 40$$

The intensity of red colour developed is proportional to cholesterol concentration and measured at 505 nm by spectrophotometer GS4701V

TRIGLYCERIDES (TGL)

(GPO-PAP) End Point

(Liquistat Kit – Bio Lab diagnostics)

Procedure

Pipette into 3 Test tubes	Blank ml	Std ml	Test ml
Distilled water	0.05	-	-
Standard	-	0.05	-
Sample	-	-	0.05
Working Reagent	1.00	1.00	1.00

Mixed well and incubated at 37°C for 10 minutes

Added 2 ml distilled water, for a 3 ml optical curvete and read at 546 nm by spectrophotometer (GS5701 V).

The final colour was stable for at least 30 mts, away from bright light.

Calculations

$$\text{Triglycerides (mg/dl)} = \frac{\text{Absorbance of Test}}{\text{Absorbance of Std}} \times 200$$

LOW DENSITY LIPOPROTEIN (LDL) AND VERY LOW DENSITY LIPOPROTEIN (VLDL)

The estimation of LDL and VLDL cholesterol was done by Friedwald calculation method.

Friedwald Calculations

$$VLDL = \frac{\text{Triglycerides}}{5}$$

$$LDL = \text{Total Cholestrol} - (\text{HDL} + \text{VDL})$$

STATISTICAL ANALYSIS

Statistics were analyzed by SPSS statistical package before and after treatment. The results were tabulated and values were presented as mean (+ or -) and SD. Students's paired 't' test P value of < 0.05 was considered to be statistically significant.

RESULTS

Study population with Age Distribution

The mean age of the study population are shown in Table 1 and Table 2. Among the three groups, 21 to 30 years of age subjects were involved maximum in the study. The mean age of subjects in group 1 was 25.63 ± 2.822 . Group 2 was 24.20 ± 3.059 and Group 3 was 24.43 ± 3.685 respectively.

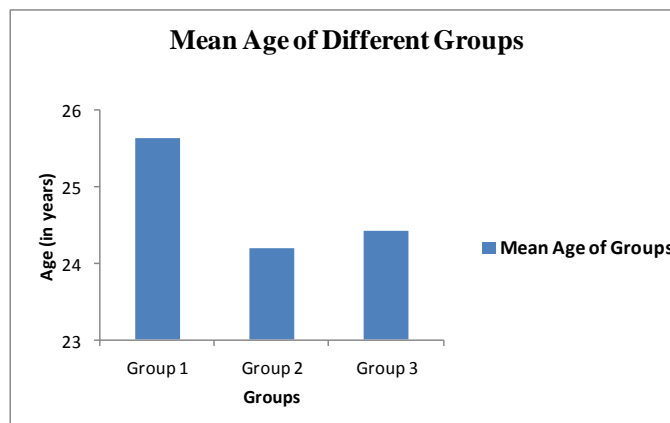
Table 1. Observations in Study population with Age distribution

Age Group Distribution (in years)	No. of subjects (n=90)	Percentage (%)
11-15	01	1.11
16-20	09	10.00
21-25	40	44.44
26-30	39	43.33
31-35	01	1.11

Table 2. Distribution of Mean Age

Group	Age (mean \pm S.D)
Group 1	25.63 ± 2.822
Group 2	24.20 ± 3.059
Group 3	24.43 ± 3.685
Total	24.75 ± 3.189

Figure 6. Distribution of mean age



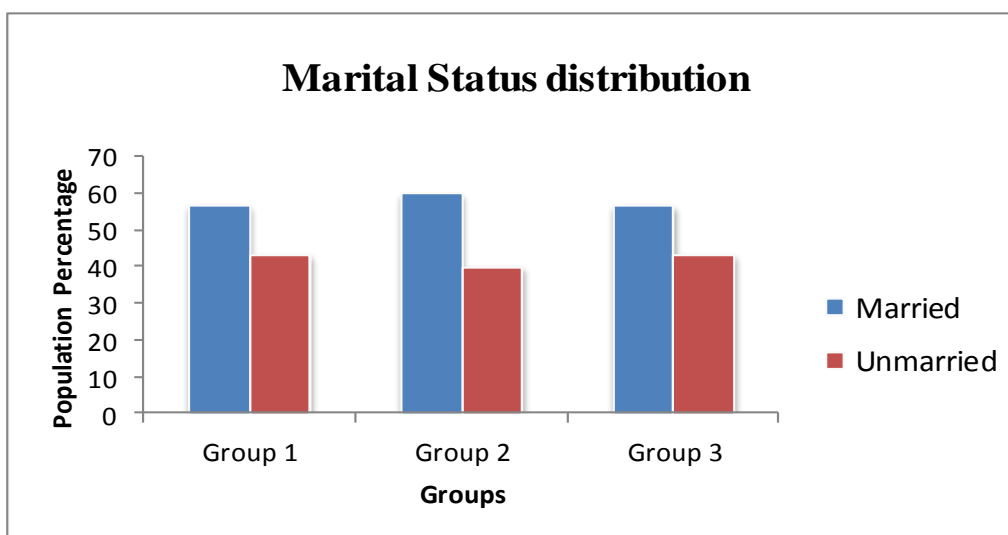
Study population with Marital Status Distribution

Marital Status Distribution of the study population is shown in Table 3. Maximum number of married women were from group 2 and followed by group 1 and group 3. In the unmarried women distribution the maximum patients were from group 1 and group 3 followed by group 2.

Table 3. Marital Status distribution

Age Group	Married		Unmarried		Total (%)
	No. of Patients	%	No. of Patients	%	
Group 1	17	56.66	13	43.33	30 (100)
Group 2	18	60	12	40	30 (100)
Group 3	17	56.66	13	43.33	30 (100)

Figure 7. Marital status distribution



Effect of MI on Weight in PCOS patients

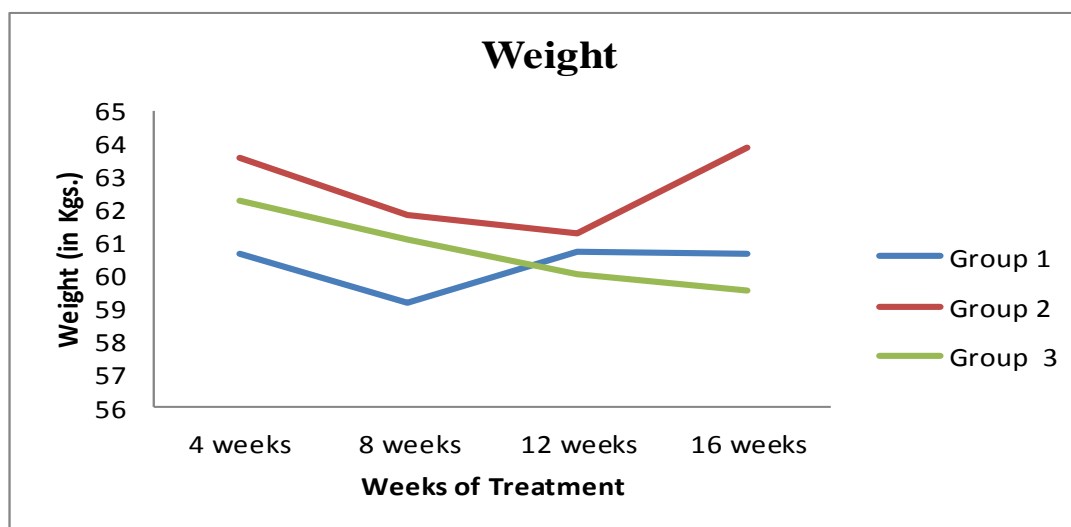
Table 4. MI Effects on weight in PCOS patients

Groups	Weight (in Kgs.)						
	0 week	4 week	8 week	12 week	16 week	20 week	24 week
Group 1	61.68± 8.50	60.65± 8.11	59.16± 13.04	60.72± 8.48	60.63± 8.33	60.27± 8.49	60.60± 8.53
Group 2	62.90± 7.92	63.57± 9.75	61.80± 7.60	61.27± 7.11	63.86± 17.25	60.63± 6.45	61.50± 5.81
Group 3	63.12± 9.40	62.27± 9.23	61.07± 8.87	60.02± 8.58	59.50± 8.64	60.62± 7.05	61.25± 7.39

Table 5. Mean difference of Weight on treatment

Groups	Mean difference of Weight (in Kgs.)					
	4 week	8 week	12 week	16 week	20 week	24 week
Group 1	1.03	2.52	0.96	1.05	1.41	1.08
Group 2	-0.67	1.1	1.63	-0.96	2.27	1.4
Group 3	0.85	2.05	3.1	3.62	2.5	1.87

Figure 8. Effect of MI on Weight in PCOS patients



Group 3 had maximum reduction of weight after 8,12,16,20 and 24 weeks and group 3 had a higher reduction of 3.1 kg at the end of 12 weeks and 3.62 kg at the end of the 16 weeks of treatment higher than all other groups. Group 1 had nominal reduction of 1.03 kg and 2.52 kg on weight at the end of 4 and 8 weeks which is higher than all other groups. It is observed that Group 3 achieved moderate control of weight than the Group 1 and 2.

It is observed that all the three groups were statistically insignificant with $p > 0.05$.

Effect of MI on BMI levels in PCOS patients

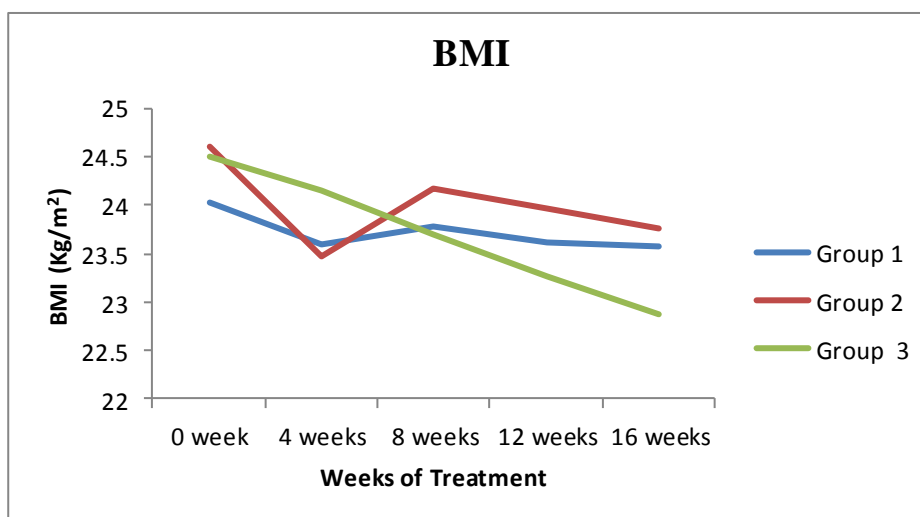
Table 6. MI Effects on BMI levels in PCOS patients

Groups	BMI (Kg/m ²)						
	0 week	4 week	8 week	12 week	16 week	20 week	24 week
Group 1	24.02± 3.17	23.60± 2.93	23.78± 2.93	23.62± 3.03	23.58± 2.89	23.44± 2.93	23.55± 2.90
Group 2	24.61± 3.17	23.48± 3.12	24.17± 2.99	23.96± 2.82	23.76± 2.47	23.78± 2.30	23.82± 2.05
Group 3	24.51± 3.83	24.16± 3.72	23.69± 3.45	23.26± 3.24	22.87± 3.27	23.31± 3.55	23.65± 4.14

Table 7. Mean difference of BMI levels on treatment

Groups	Mean difference of BMI (Kg/m ²)					
	4 week	8 week	12 week	16 week	20 week	24 week
Group 1	0.42	0.24	0.4	0.44	0.58	0.47
Group 2	1.13	0.44	0.65	0.85	0.88	0.79
Group 3	0.35	0.82	1.25	1.64	1.2	0.86

Figure 9. Effect of MI on BMI levels in PCOS patients



Group 3 had maximum reduction of BMI after 8,12,16,20 and 24 weeks treatment and group 3 had a higher reduction of 1.64 kg/m² at the end of 16 weeks which is higher than all other groups. Group 2 had nominal reduction of 1.13 kg/m² on BMI at 4 weeks treatment which is higher than all other groups. It is observed that Group 3 achieved moderate control of BMI than the Group 1 and 2. It is observed that all the three groups were statistically insignificant because of p value >0.05.

Effect of MI on Fasting blood glucose level in PCOS patients

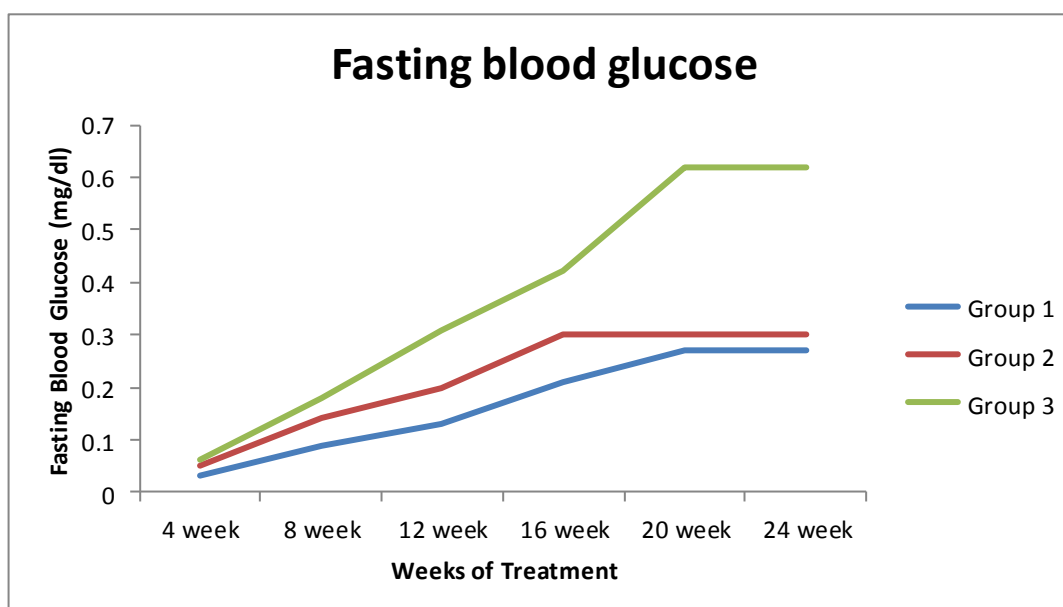
Table 8. MI Effects on fasting blood glucose in PCOS patients

Groups	Fasting Blood Glucose (mg/dl)						
	0 week	4 week	8 week	12 week	16 week	20 week	24 week
Group 1	83.13± 8.47	83.10± 9.95	83.04± 8.96	83.00± 7.03	82.92± 7.71	82.86± 14.61	82.86± 8.17
Group 2	83.47± 9.71	83.42± 9.37	83.33± 8.66	83.27± 8.79	83.17± 9.85	83.17± 8.38	83.17± 6.02
Group 3	83.33± 8.84	83.27± 10.12	83.15± 8.34	83.02± 8.02	82.91± 8.70	82.71± 10.44	82.71± 8.60

Table 9. Fasting blood glucose levels during treatment based on Mean difference

Groups	Mean difference of Fasting Blood Glucose (mg/dl)					
	4 week	8 week	12 week	16 week	20 week	24 week
Group 1	0.03	0.09	0.13	0.21	0.27	0.27
Group 2	0.05	0.14	0.20	0.30	0.30	0.30
Group 3	0.06	0.18	0.31	0.42	0.62	0.62

Figure 10. Effect of MI on fasting blood glucose levels in PCOS patients



Mean reduction in FBS was shown in Table 6. Group 3 shows insignificant nominal reduction of FBS by 20 and 24 weeks (0.62 mg %) with statistical value of $P > 0.05$ but it is higher than group 1 & 2 for the reduction in FBS. The mean difference in reduction of fasting blood glucose after 4, 8, 12, 16, 20 and 24 weeks between the groups was not statistically significant.

Effect of MI on Post Prandial blood glucose level in PCOS patients

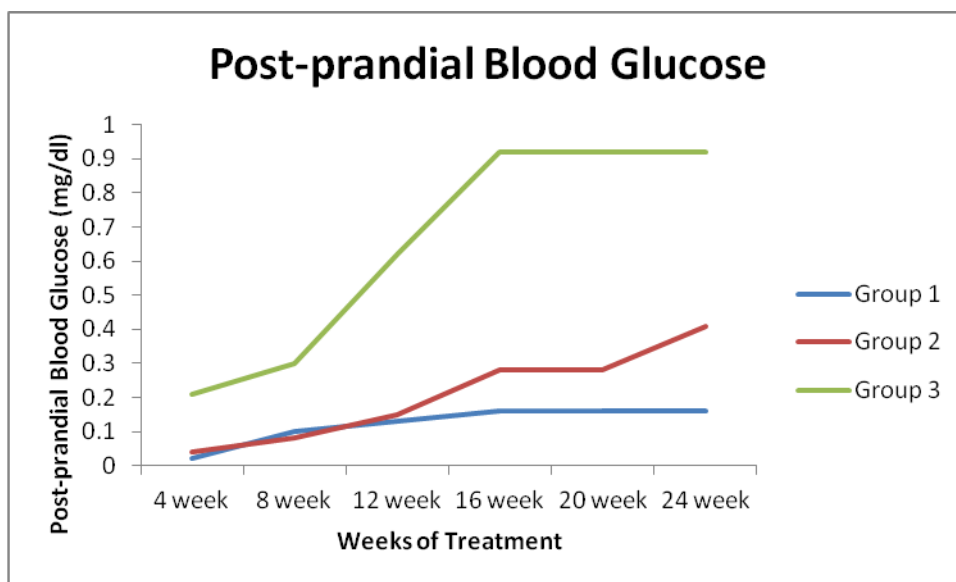
Table 10. Effect of MI on Postprandial blood glucose level in PCOS patients

Groups	Postprandial Blood Glucose(mg/dl)						
	0 week	4 week	8 week	12 week	16 week	20 week	24 week
Group 1	102.13± 16.17	102.11± 14.03	102.03± 10.80	102.00± 11.52	101.97± 12.51	101.97± 11.75	101.97± 11.74
Group 2	94.43± 16.18	94.39± 14.25	94.35± 13.71	94.28± 25.68	94.15± 20.77	94.15± 13.78	94.02± 11.05
Group 3	103.93± 18.62	103.73± 12.34	103.63± 12.03	103.31± 12.04	103.01± 13.18	103.01± 5.17	103.01± 4.17

Table 11. Mean difference of post-prandial blood glucose on treatment

Groups	Mean difference of Postprandial Blood Glucose(mg/dl)					
	4 week	8 week	12 week	16 week	20 week	24 week
Group 1	0.02	0.1	0.13	0.16	0.16	0.16
Group 2	0.04	0.08	0.15	0.28	0.28	0.41
Group 3	0.21	0.30	0.62	0.92	0.92	0.92

Figure 11. Effect of MI on postprandial blood glucose levels in PCOS patients



Group 3 subjects had nominal reduction of 0.92 mg % after 16 weeks ($P>0.05$) followed by Group 2 which had a minimal reduction of 0.28 mg % after 16 weeks ($P>0.05$). But it is found that all the three groups were not statistically significant.

Effect of MI on Fasting Insulin level in PCOS patients

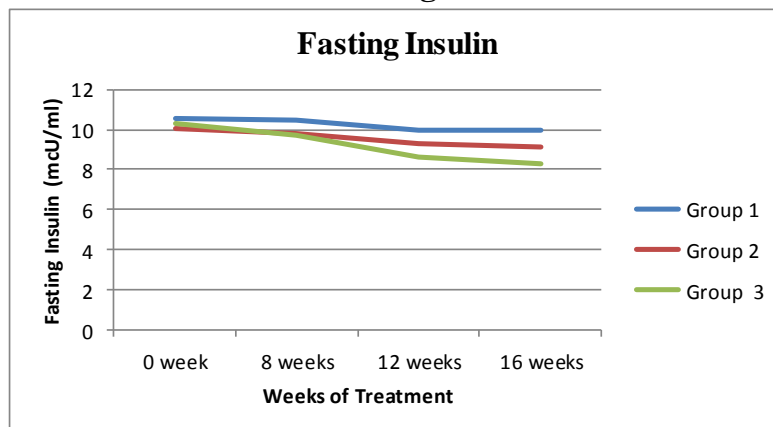
Table 12. MI Effects on Fasting Insulin level in PCOS patients

Groups	Fasting Insulin (mg)						
	0 week	4 week	8 week	12 week	16 week	20 week	24 week
Group 1	10.55± 3.77	10.55± 3.77	10.50± 3.71	9.96± 3.39	9.987± 3.41	9.75± 3.28	10.22± 3.45
Group 2	10.04± 4.60	10.04± 4.20	9.78± 4.18	9.31± 3.64	9.16± 3.47	8.96± 3.26	9.06± 3.01
Group 3	10.31± 3.64	10.06± 3.38	9.69± 2.85	8.59± 2.33	8.27± 2.43	9.47± 2.87	10.15± 3.39

Table 13. Mean difference of Fasting Insulin on treatment

Groups	Mean difference of Fasting Insulin					
	4 week	8 week	12 week	16 week	20 week	24 week
Group 1	0	0.05	0.59	0.56	0.8	0.33
Group 2	0.01	0.26	0.73	0.88	1.08	0.98
Group 3	0.25	0.62	1.72	2.04	0.84	0.16

Figure 12. Effect of MI on Fasting Insulin levels in PCOS patients



Maximum reduction of fasting insulin after 4,8,12 and 16 weeks under group 3 had a mean reduction of 1.72 mg% at the end of 12 weeks and 2.04 mg % after the 16 weeks of treatment higher than the other two groups. Group 2 had nominal reduction of 1.08 mg% on fasting insulin after 20 weeks of treatment higher than all other groups.

The mean difference in reduction of fasting insulin after 4 weeks between the groups was not statistically significant except for Group 3. It is found that Group 3 achieved average glycaemic control of fasting insulin than the Group 1 &2.

The mean difference in reduction of fasting insulin after 8 weeks between the groups was not statistically significant except for Group 2 and Group 3. Myoinositol achieved moderate glycaemic control of fasting insulin than the Placebo and Metformin.

The mean difference in reduction of fasting insulin for group 3 after 12 weeks and 16 weeks were statistically significant with $P < 0.05$ on comparing with other groups. Group 3 achieved higher glycaemic control of fasting insulin than Group 1 & 2.

Effect of MI on LH levels in PCOS patients

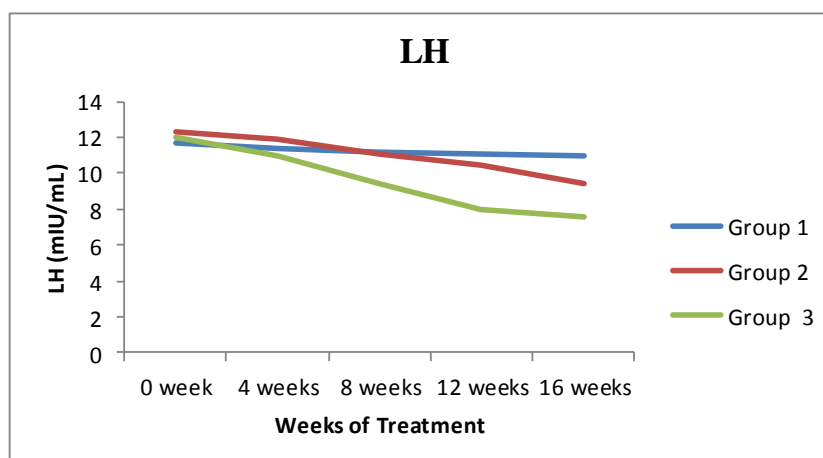
Table 14. MI Effects on LH levels in PCOS patients

Groups	LH (mIU/mL)						
	0 week	4 week	8 week	12 week	16 week	20 week	24 week
Group 1	11.66± 1.64	11.37± 1.58	11.16± 1.74	11.13± 1.84	10.97± 1.99	10.79± 2.19	11.03± 2.11
Group 2	12.33± 1.58	11.87± 1.55	11.11± 1.46	10.47± 1.38	9.40± 1.90	9.21± 1.26	8.75± 1.30
Group 3	12.03± 1.42	11.03± 1.68	9.43± 1.57	7.99± 1.66	7.56± 1.61	8.68± 1.73	10.00± 0.25

Table 15. Mean difference of LH levels on treatment

Groups	Mean difference of LH (mIU/mL)					
	4 week	8 week	12 week	16 week	20 week	24 week
Group 1	0.29	0.5	0.53	0.69	0.87	0.63
Group 2	0.46	1.22	1.86	2.93	3.12	3.58
Group 3	1	2.6	4.04	4.47	3.35	2.03

Figure 13. Effect of MI on LH levels in PCOS patients



Group 2 subjects had moderate reduction of LH after 8,12,16,20 and 24 weeks with the corresponding comparison based on p values such as when p is i) $0.003728000 < 0.01$ ii) $0.000015000 < 0.0001$ iii) $0.000000035 < 0.0001$ iv) $0.000000000 < 0.0001$ and v) $0.000000001 < 0.0001$ respectively. Group 2 was statistically most significant during 12, 16, 20 and 24 weeks and Group 2 achieved moderate control of LH than the Group 1.

Group 3 subjects had significant reduction of LH after 4,8,12,16,20 and 24 weeks with the corresponding comparison based on p values such as when p is i) $0.01787 < 0.05$

ii)0.0000000156<0.0001 iii)0.00000000000000465<0.0001 iv)0.00000000000252<0.0001 v)0.001057<0.001 and vi)0.000000293<0.0001 respectively . It is found that Group 3 achieved more statistical significant ($p<0.0001$) during 8, 12 and 16 weeks with a high control of LH than the Group 1 and Group 2.

Effect of MI on FSH levels in PCOS patients

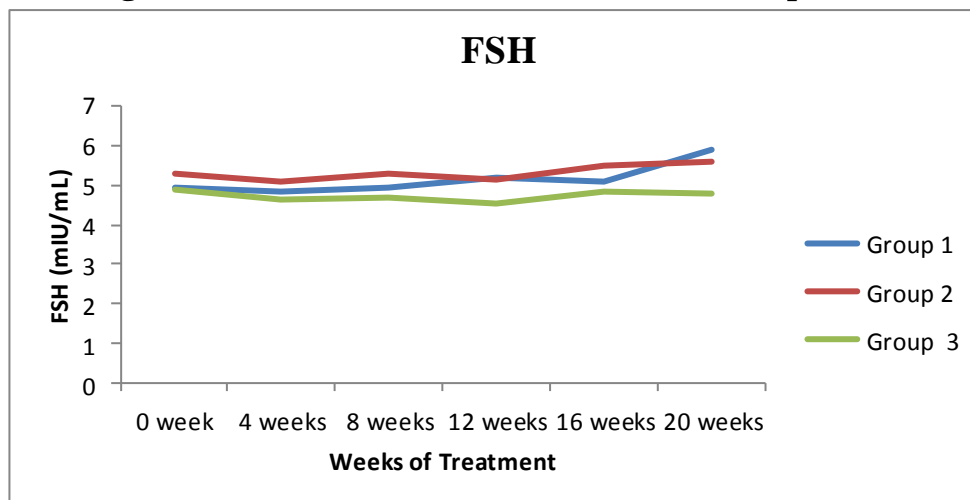
Table 16. MI Effects on FSH levels in PCOS patients

Groups	FSH (mIU/mL)						
	0 week	4 week	8 week	12 week	16 week	20 week	24 week
Group 1	4.94±0.94	4.83±0.97	4.95±1.04	5.18±1.28	5.08±1.36	4.01±2.13	4.16±1.95
Group 2	5.30±0.86	5.10±0.83	5.30±0.78	5.13±0.73	5.49±1.30	5.57±1.21	5.47±0.94
Group 3	4.89±0.69	4.64±0.65	4.66±0.55	4.53±0.71	4.83±0.82	4.77±0.45	5.05±0.85

Table 17. Mean difference of FSH on treatment

Groups	Mean difference of FSH (mIU/mL)					
	4 week	8 week	12 week	16 week	20 week	24 week
Group 1	0.11	-0.01	-0.24	-0.14	0.93	0.78
Group 2	0.2	0	0.17	-0.19	-0.27	-0.17
Group 3	0.25	0.23	0.36	0.06	0.12	-0.16

Figure 14. Effect of MI on FSH levels in PCOS patients



Group 3 had maximum reduction of FSH after 4,8,12 and 16 weeks treatment and group 1 had a higher reduction of 0.93 at the end of 20 weeks than all other groups. The mean difference in reduction of FSH after 20 weeks for the group 1 was statistically significant than group 2 and 3. It is found that group 1 and group 3 achieved average control of FSH than the group 2.

Group 1 was statistically significant at the end of 20 week ($p < 0.05$) compare to other groups.

Effect of MI on LH /FSH Ratio in PCOS patients

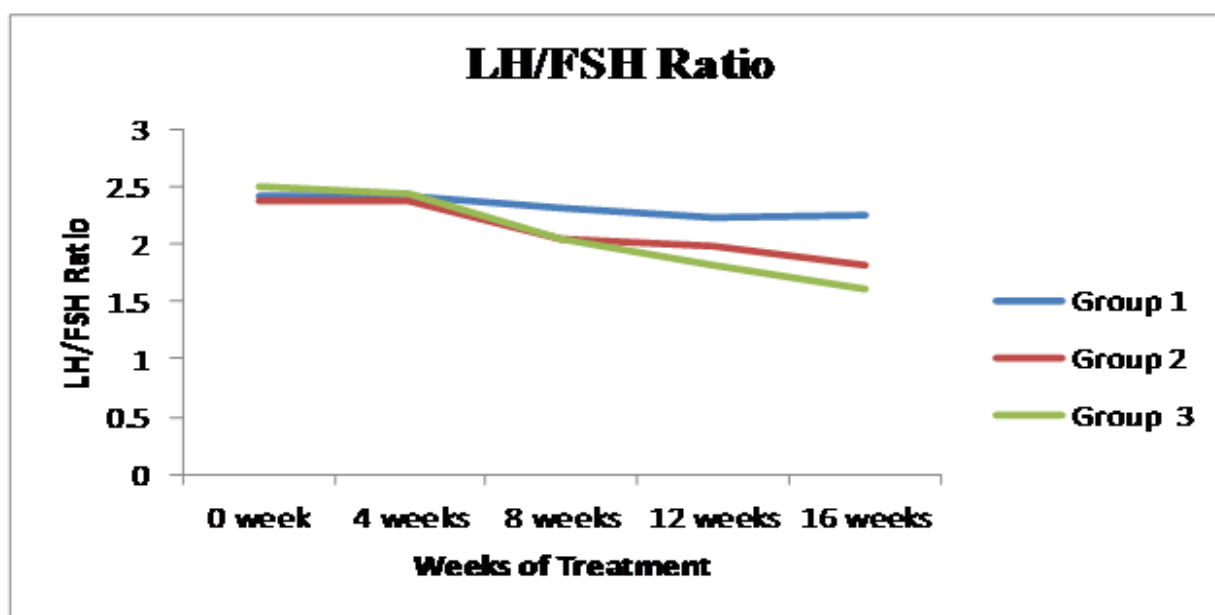
Table 18. MI Effects on LH /FSH Ratio in PCOS patients

Groups	LH/ FSH Ratio						
	0 week	4 week	8 week	12 week	16 week	20 week	24 week
Group 1	2.42±0.45	2.41±0.42	2.31±0.41	2.23±0.43	2.26±0.54	2.05±0.66	2.13±0.68
Group 2	2.37±0.42	2.37±0.42	2.04±0.51	1.99±0.48	1.81±0.50	1.74±0.46	1.64±0.36
Group 3	2.50±0.40	2.43±0.50	2.05±0.39	1.81±0.47	1.61±0.41	1.84±0.3	2.03±0.33

Table 19. Mean difference of LH/FSH Ratio on treatment

Groups	Mean difference of LH/FSH Ratio					
	4 week	8 week	12 week	16 week	20 week	24 week
Group 1	0.01	0.11	0.19	0.16	0.37	0.29
Group 2	0	0.33	0.38	0.56	0.63	0.73
Group 3	0.07	0.45	0.69	0.89	0.66	0.47

Figure 15. Effect of MI on LH/FSH ratio in PCOS patients



The mean LH/FSH level were lowered by the drugs Group 3 and Group 2 and this reduction of LH/FSH level by both drugs after 8,12,16,20 weeks showed statistical significance ($p < 0.05$). Maximum reduction of LH/FSH level after 16 weeks was observed in group 3. It is observed that group 3 had significant reduction of LH/FSH ratio after 4,8,12,16 and 20 weeks than Group 2 and Group 1. Group 3 achieved significant control of LH/FSH than the Group 1 and 2.

Over all Group 2 was statistically significant at the end of 8 and 12 weeks ($p < 0.01$) and statistically most significant during 16, 20, 24 weeks ($p < 0.0001$) and Group 3 shows statistically most significance from 8 weeks onwards ($p < 0.0001$). It is observed that Group 3 had higher control of LH/FSH compared with other groups.

Effect of MI on TSH levels in PCOS patients

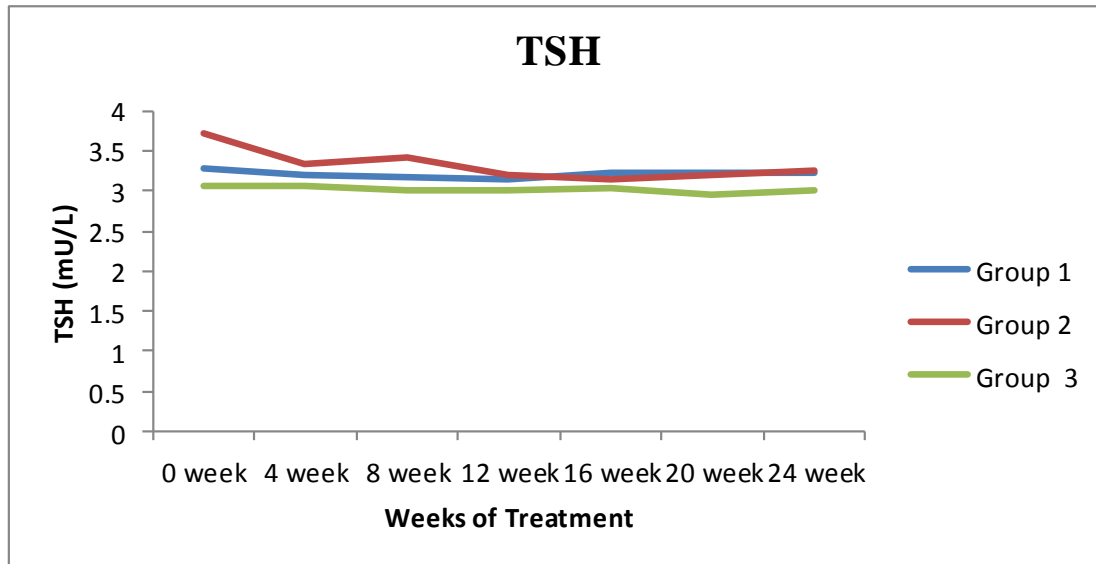
Table 20. MI Effects on TSH levels in PCOS patients

Groups	TSH (mU/L)						
	0 week	4 week	8 week	12 week	16 week	20 week	24 week
Group 1	3.29±1.41	3.19±1.41	3.17±1.40	3.14±1.40	3.22±1.42	3.22±1.41	3.24±1.41
Group 2	3.73±1.36	3.33±0.79	3.43±1.48	3.19±0.77	3.15±0.79	3.20±0.69	3.25±0.66
Group 3	3.07±0.66	3.07±0.65	3.01±0.63	3.01±0.64	3.03±0.62	2.96±0.59	3.02±0.41

Table 21. Mean difference of TSH on treatment

Groups	Mean difference of TSH (mU/L)					
	4 week	8 week	12 week	16 week	20 week	24 week
Group 1	0.1	0.12	0.15	0.07	0.07	0.05
Group 2	0.4	0.3	0.54	0.58	0.53	0.48
Group 3	0	0.06	0.06	0.04	0.11	0.05

Figure 16. Effect of MI on TSH levels in PCOS patients



The TSH levels on 12 week for group 3 was showed statistical significance with $p < 0.05$ than all other groups. Group 2 achieved moderate TSH reduction than other two groups.

Effect of MI on Prolactin levels in PCOS patients

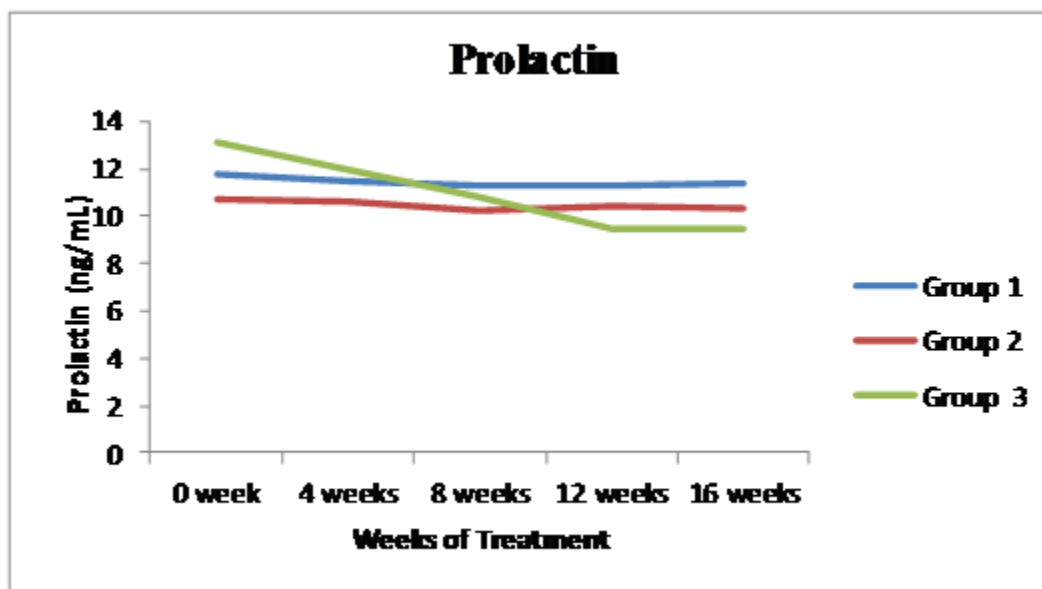
Table 22. MI Effects on Prolactin levels in PCOS patients

Groups	Prolactin (ng/mL)						
	0 week	4 week	8 week	12 week	16 week	20 week	24 week
Group 1	11.77± 3.32	11.43± 3.27	11.30± 3.19	11.33± 3.31	11.38± 3.31	11.54± 3.26	11.58± 3.24
Group 2	10.68± 2.65	10.58± 1.79	10.26± 2.10	10.42± 1.69	10.29± 1.90	10.25± 1.93	10.26± 1.94
Group 3	13.14± 3.94	11.95± 3.31	10.85± 2.86	9.47± 2.61	9.44± 2.26	9.69± 2.54	10.22± 1.89

Table 23. Mean difference of Prolactin levels on treatment

Groups	Mean difference of Prolactin (ng/mL)					
	4 week	8 week	12 week	16 week	20 week	24 week
Group 1	0.34	0.47	0.44	0.39	0.23	0.19
Group 2	0.10	0.06	0.42	0.26	0.43	0.42
Group 3	1.19	2.29	3.67	3.7	3.45	2.92

Figure 17. Effect of MI on Prolactin levels in PCOS patients



Group 3 lowered the mean prolactin levels after 4,8,12,16,20 and 24 weeks and this reduction of prolactin levels after 8,12,16 and 20 weeks was most statistically significant with the corresponding comparison based on p values such as when p is i) $0.01436 < 0.01$ ii) $p = 0.000119 < 0.0001$ iii) $0.000135 < 0.0001$ and iv) $0.011293 < 0.01$. It is observed that Group 3 achieved higher control of prolactin than the Group 1 and Group 2.

Effect of MI on T. Testosterone levels in PCOS patients

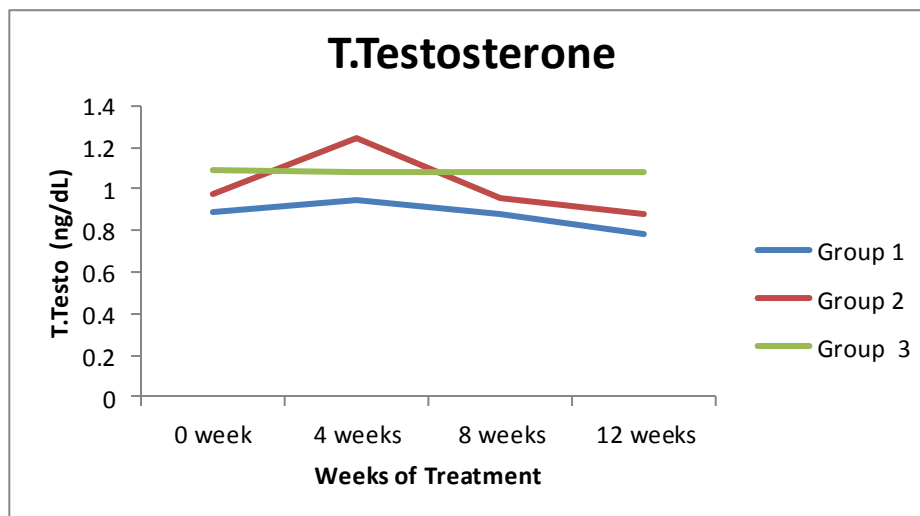
Table 24. MI Effects on T. Testosterone levels in PCOS patients

Groups	T. Testosterone (ng/dL)						
	0 week	4 week	8 week	12 week	16 week	20 week	24 week
Group 1	0.89±0.38	0.95±0.53	0.88±0.39	0.78±0.36	0.78±0.36	0.78±0.36	0.85±0.37
Group 2	0.97±0.24	1.24±1.38	0.96±0.24	0.88±0.28	0.88±0.27	0.93±0.22	0.93±0.16
Group 3	1.09±0.99	1.08±0.99	1.08±0.99	1.08±0.99	1.23±1.12	1.40±1.34	1.77±1.75

Table 25. Mean difference of T. Testosterone on treatment

Groups	Mean difference of T. Testosterone (ng/dL)					
	4 week	8 week	12 week	16 week	20 week	24 week
Group 1	-0.06	0.01	0.11	0.11	0.11	0.04
Group 2	-0.27	0.01	0.09	0.14	0.04	0.04
Group 3	0.01	0.01	0.01	-0.14	-0.31	-0.68

Figure 18. Effect of MI on T. Testosterone levels in PCOS patients



The mean difference in reduction of T.Testosterone after 4 weeks for group 3 was comparatively better than group 1 and 2. The mean difference in reduction of T.Testo at 8 weeks for all the groups were significant. All the three groups are equally contributed towards the reduction of T.Testosterone over the periods and not statistically significant.

Effect of MI on Free Testosterone levels in PCOS patients

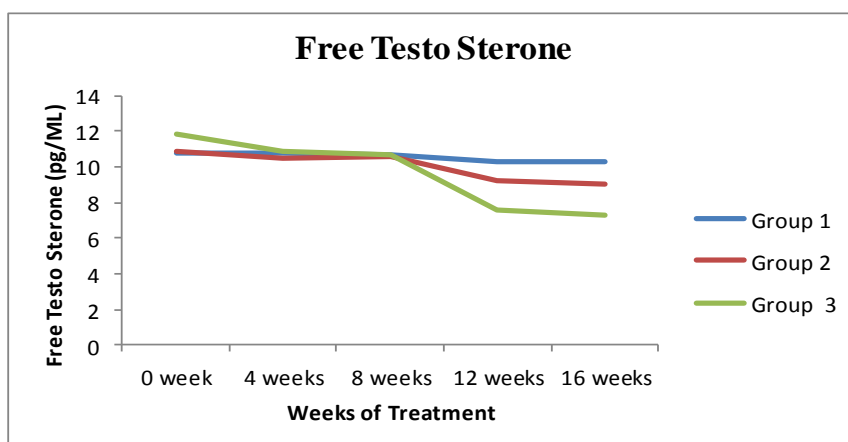
Table 26. MI Effects on Free Testosterone levels in PCOS patients

Groups	Free Testo Sterone (pg/ML)						
	0 week	4 week	8 week	12 week	16 week	20 week	24 week
Group 1	10.78± 5.19	10.76± 5.18	10.70± 5.18	10.29± 4.93	10.31± 4.92	10.21± 4.99	10.50± 5.29
Group 2	10.91± 4.11	10.46± 4.41	10.59± 4.04	9.27± 3.18	9.08± 3.24	8.36± 3.17	8.71± 2.56
Group 3	11.85± 6.33	10.87± 5.53	10.66± 5.42	7.61± 3.29	7.26± 3.10	8.43± 3.67	8.52± 2.93

Table 27. Mean difference of Free Testosterone levels on treatment

Groups	Mean difference of Free Testosterone					
	4 week	8 week	12 week	16 week	20 week	24 week
Group 1	0.02	0.08	0.49	0.47	0.57	0.28
Group 2	0.45	0.32	1.64	1.83	2.55	2.20
Group 3	0.98	1.19	4.24	4.59	3.42	3.33

Figure 19. Effect of MI on Free Testosterone levels in PCOS patients



Reduction of Free Testosterone after 4, 8, 12, 16, 20 and 24 weeks among the Group 3 and Group 2 was statistically significant and was maximum in Group 3 at the end of 16 weeks (4.59%) and group 2 at the end of 20 weeks (2.55%). On reducing the Free Testosterone the significant improvement is observed in group 3 at the earlier stage and also at the end of 4, 8, 12, 16, 20 and 24 weeks. The mean difference in reduction of Free Testosterone after 4 weeks between the group 3 and group 2 was statistically significant except for Group 1. It is found that Group 3 achieved higher control of Free Testosterone than the Group 1 & 2.

The mean difference in reduction of Free Testosterone after 8 weeks for the group 3 was statistically significant than the other Groups 1 and 2. Group 3 achieved higher control of Free Testosterone than the Group 1 & 2.

The mean difference in reduction of Free Testosterone for group 2 after 20 weeks was statistically more significant with $p < 0.01$ and also on 24 weeks with $p < 0.05$.

The mean difference in reduction of Free Testosterone for group 3 after 12 weeks showed statistical significance with p value of 0.01 and 16 weeks was statistically most significant ($p < 0.001$). Group 3 achieved higher control of Free Testosterone and treatment with Group 3 was better than the Group 1 and Group 2.

Effect of MI on S. Androstenedione levels in PCOS patients

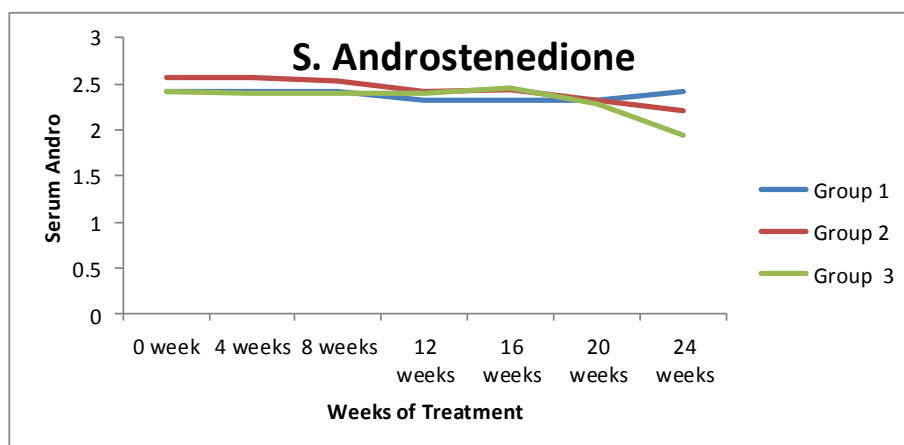
Table 28. MI Effects on S.Androstenedione levels in PCOS patients

Groups	S.Androstenedione						
	0 week	4 week	8 week	12 week	16 week	20 week	24 week
Group 1	2.41±0.70	2.41±0.70	2.41±0.70	2.32±0.69	2.32±0.69	2.32±0.69	2.41±0.70
Group 2	2.57±0.89	2.57±0.88	2.54±0.88	2.41±0.83	2.43±0.84	2.32±0.77	2.20±0.86
Group 3	2.41±0.83	2.40±0.88	2.40±0.83	2.40±0.82	2.46±0.95	2.29±0.65	1.94±0.66

Table 29. Mean difference of S. Androstenedione on treatment

Groups	Mean difference of S.Androstenedione					
	4 week	8 week	12 week	16 week	20 week	24 week
Group 1	0.00	0.00	0.09	0.09	0.09	0.00
Group 2	0.00	0.03	0.16	0.14	0.25	0.37
Group 3	0.01	0.01	0.01	0.05	0.12	0.47

Figure 20. Effect of MI on S. Androstenedione levels in PCOS patients



The mean difference in reduction of S. Androstenedione after 8,12,16,20 weeks for group 2 was better than group 1 and 3. The mean difference in reduction of S. Androstenedione at 4 weeks for group 3 was significant. Group 2 followed by Group 3 achieved moderate reduction of S. Androstenedione over the periods.

Effect of MI on DHEA-S levels on PCOS patients

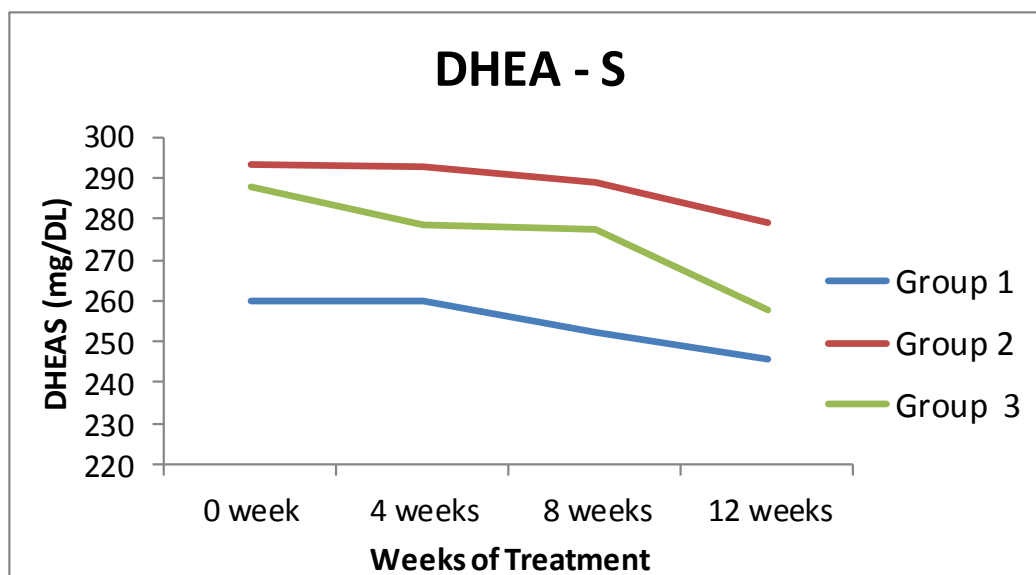
Table 30. MI Effects on DHEA-S levels on PCOS patients

Groups	DHEAS (mg/DL)						
	0 week	4 week	8 week	12 week	16 week	20 week	24 week
Group 1	259.95± 45.02	259.77± 45.22	252.47± 54.95	245.94± 63.03	255.90± 44.87	255.33± 44.97	258.37± 44.10
Group 2	293.21± 62.04	292.46± 59.63	289± 61.14	278.90± 55.85	276.90± 56.97	273.81± 65.95	284.11± 61.59
Group 3	287.78± 85.28	278.40± 86.46	277.60± 80.09	257.51± 73.40	264.61± 77.20	260.75± 15.29	267.25± 11.12

Table 31. Mean difference of DHEA-S levels on treatment

Groups	Mean difference of DHEAS (mg/DL)					
	4 week	8 week	12 week	16 week	20 week	24 week
Group 1	0.18	7.48	14.01	4.05	4.62	1.58
Group 2	0.75	4.21	14.31	16.31	19.4	9.1
Group 3	9.38	10.18	30.27	23.17	27.03	20.53

Figure 21. Effect of MI on DHEA-S levels in PCOS patients



The mean difference in reduction of DHEA-S for group 2 after 16 and 20 weeks was statistically significant with the p value of 0.030895 and 0.016644 which is less than the chosen significance level ($p < 0.05$). Group 2 achieved moderate control of DHEA-S.

The mean difference in reduction of DHEA-S for group 3 after 12, 16, 20 and 24 weeks was statistically significant with the corresponding values of p i) $0.03446 < 0.05$ ii) $0.045497 < 0.05$ iii) $0.011193 < 0.01$ and iv) $0.02332 < 0.05$. It is found that Group 3 was most significant by 20 week ($p < 0.01$). Group 3 achieved higher control of DHEA-S and treatment with Group 3 was better than the Group 1 and 2.

Effect of MI on Total Cholesterol in PCOS patients

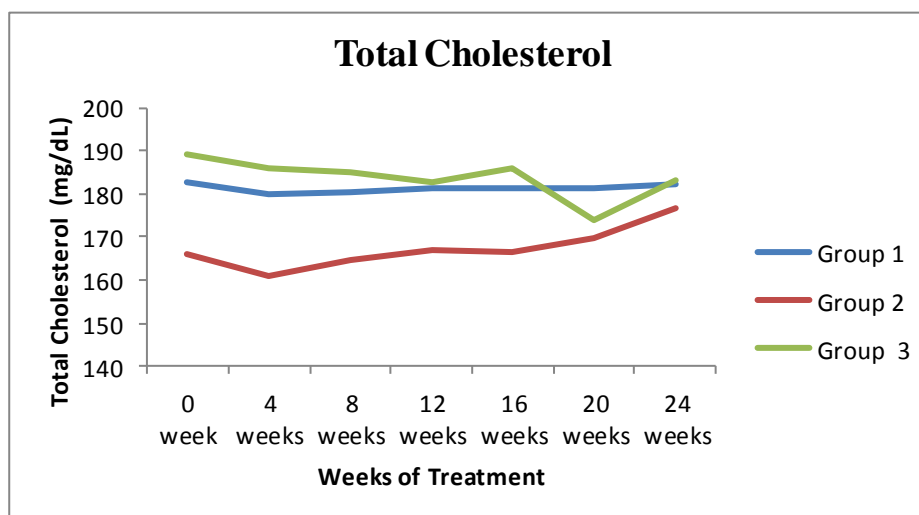
Table 32. MI Effects on Total Cholesterol in PCOS patients

Groups	Total Cholesterol (mg/dL)						
	0 week	4 week	8 week	12 week	16 week	20 week	24 week
Group 1	182.93± 23.00	179.92± 23.21	180.37± 23.00	181.24± 21.99	181.31± 21.92	181.28± 23.18	182.24± 23.02
Group 2	166.01± 26.54	160.79± 19.32	164.83± 25.60	166.95± 25.77	166.65± 24.00	169.91± 26.65	176.50± 28.99
Group 3	189.11± 26.60	186.15± 25.92	185.02± 24.94	182.85± 23.62	186.18± 25.47	173.7± 19.28	183.4± 7.13

Table 33. Mean difference of Total cholesterol on treatment

Groups	Mean difference of Total Cholesterol (mg/dL)					
	4 week	8 week	12 week	16 week	20 week	24 week
Group 1	3.02	2.56	1.70	1.62	1.66	0.69
Group 2	5.22	1.18	-0.94	-0.64	-3.90	-10.49
Group 3	2.96	4.09	6.26	2.93	15.42	5.72

Figure 22. Effect of MI on Total Cholesterol levels in PCOS patients



Group 3 controlled the mean total cholesterol levels after ,8,12,16,20 and 24 weeks and it was statistically significant by 20 weeks ($p<0.05$). It is observed that Group 3 achieved higher control of TC than the Group 1 and Group 2.

Effect of MI on Triglycerides in PCOS patients

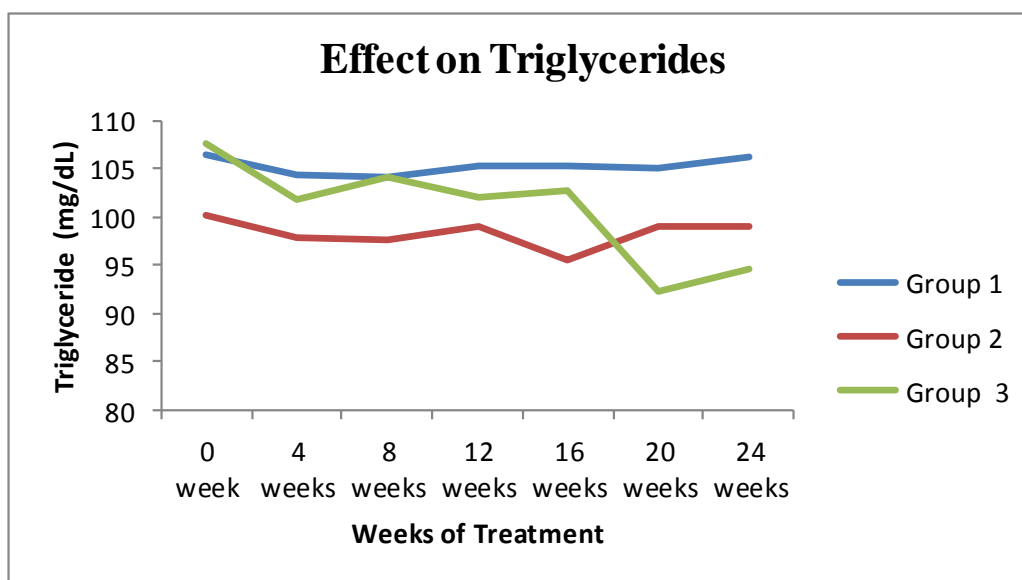
Table 34. MI Effects on Triglycerides in PCOS patients

Groups	Triglyceride (mg/dL)						
	0 week	4 week	8 week	12 week	16 week	20 week	24 week
Group 1	106.43± 19.66	104.41± 19.73	104.11± 19.48	105.35± 19.67	105.21± 20.13	105.13± 20.28	106.14± 19.54
Group 2	100.08± 14.60	97.82± 12.15	97.69± 12.12	99.11± 13.03	95.44± 10.10	99.04± 13.88	99.04± 16.20
Group 3	107.73± 21.51	101.73± 23.69	104.07± 20.82	101.97± 20.63	102.72± 20.96	92.25± 5.70	94.50± 6.06

Table 35. Mean difference of Triglycerides on treatment

Groups	Mean differences of Triglyceride (mg/dL)					
	4 week	8 week	12 week	16 week	20 week	24 week
Group 1	2.02	2.32	1.08	1.22	1.3	0.29
Group 2	2.26	2.39	0.97	4.64	1.04	1.04
Group 3	6	3.66	5.76	5.01	15.4	13.23

Figure 23. Effect of MI on Triglyceride levels in PCOS patients



Group 3 significantly reduces Triglycerides levels after 4,8,12,16,20 and 24 weeks of treatment and maximum reduction was shown at 20 weeks (15.48%) and this reduction of triglycerides levels after 20 weeks and 24 weeks was statistically significant with the corresponding values of ($p=0.001608<0.01$) and ($p=0.025888<0.05$). It is observed that Group 3 achieved significant control of triglycerides than the Group 1 and 2.

Effect of MI on LDL Cholesterol levels in PCOS patients

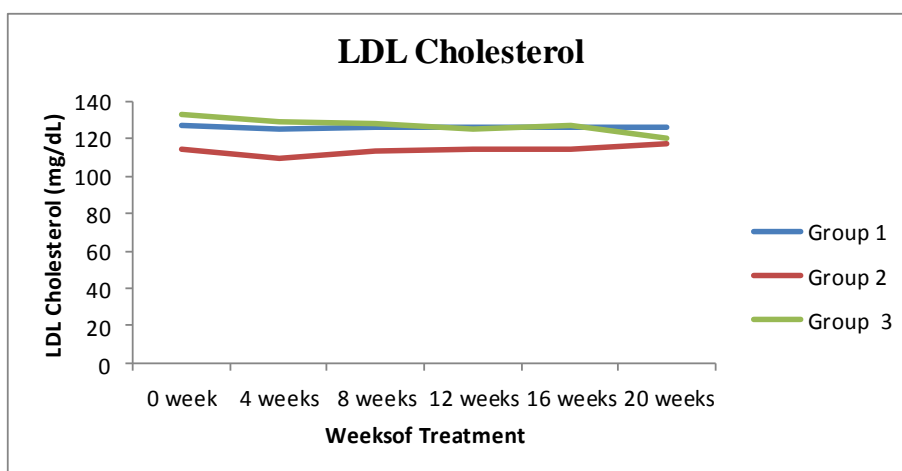
Table 36. MI Effects on LDL Cholesterol levels in PCOS patients

Groups	LDL Cholesterol (mg/dL)						
	0 week	4 week	8 week	12 week	16 week	20 week	24 week
Group 1	127.20± 20.27	125.49± 20.29	125.73± 20.10	126.47± 19.53	126.47± 19.39	126.33± 19.86	126.86± 20.21
Group 2	113.93± 24.34	109.83± 18.44	113.34± 22.94	114.21± 23.19	114.41± 23.73	116.88± 23.88	116.88± 25.44
Group 3	132.53± 5.68	129.47± 23.16	127.58± 22.13	125.08± 20.84	127.44± 23.52	119.75± 17.48	130.00± 8.12

Table 37. Mean difference of LDL Cholesterol levels on treatment

Groups	Mean Difference of LDL Cholesterol(mg/dL)					
	4 week	8 week	12 week	16 week	20 week	24 week
Group 1	1.71	1.47	0.73	0.73	0.87	0.34
Group 2	4.1	0.59	-0.28	-0.48	-2.95	-2.95
Group 3	3.06	4.95	7.45	5.09	12.78	2.53

Figure 24. Effect of MI on LDL Cholesterol levels in PCOS patients



Reduction of LDL Cholesterol after 8,12,16,20 and 24 weeks for Group 3 was good and reduction for Group 1 was average and the maximum reduction was shown in Group 3 at 20 weeks (12.78%) . The improvement in the reduction of LDL Cholesterol was shown in the group 3 at the earlier stage such as 8,12,16,20 and 24 weeks.

The mean difference in reduction of LDL Cholesterol after 12 weeks for group 3 was comparatively better than group 1 and group 2. It is found that Group 3 achieved higher control of LDL Cholesterol than the Group 1 and Group 2.

The mean difference in reduction of LDL Cholesterol after 16 weeks for the group 3 was better than other groups. Group 3 achieved higher control of LDL than the Group 1 and 2. It is found that all the three groups were statistically insignificant due to $p > 0.05$.

Effect of MI on HDL Cholesterol levels in PCOS patients

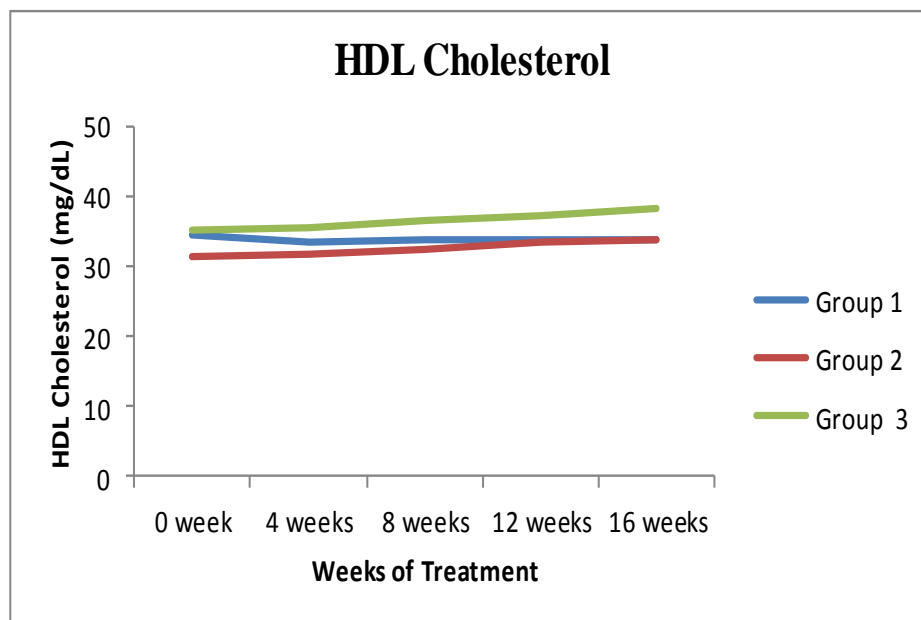
Table 38. MI Effects on HDL Cholesterol levels in PCOS patients

Groups	HDL Cholesterol						
	0 week	4 week	8 week	12 week	16 week	20 week	24 week
Group 1	34.44± 4.91	33.55± 4.18	33.81± 4.33	33.70± 4.55	33.80± 3.98	33.92± 4.35	34.15± 4.46
Group 2	31.40± 2.64	31.73± 2.71	32.40± 2.69	33.40± 2.64	33.63± 2.56	33.85± 2.79	33.824± 2.48
Group 3	35.04± 5.68	35.67± 5.69	36.63± 5.56	37.38± 5.46	38.21± 6.41	35.50± 2.78	35.50± 3.28

Table 39. Mean difference of HDL Cholesterol levels on treatment

Groups	Mean difference of HDL Cholesterol					
	4 week	8 week	12 week	16 week	20 week	24 week
Group 1	-0.89	-0.63	-0.74	-0.64	-0.52	-0.29
Group 2	0.33	1.00	2.00	2.23	2.45	2.42
Group 3	0.63	1.59	2.34	3.17	0.46	0.46

Figure 25. Effect of MI on HDL Cholesterol levels in PCOS patients

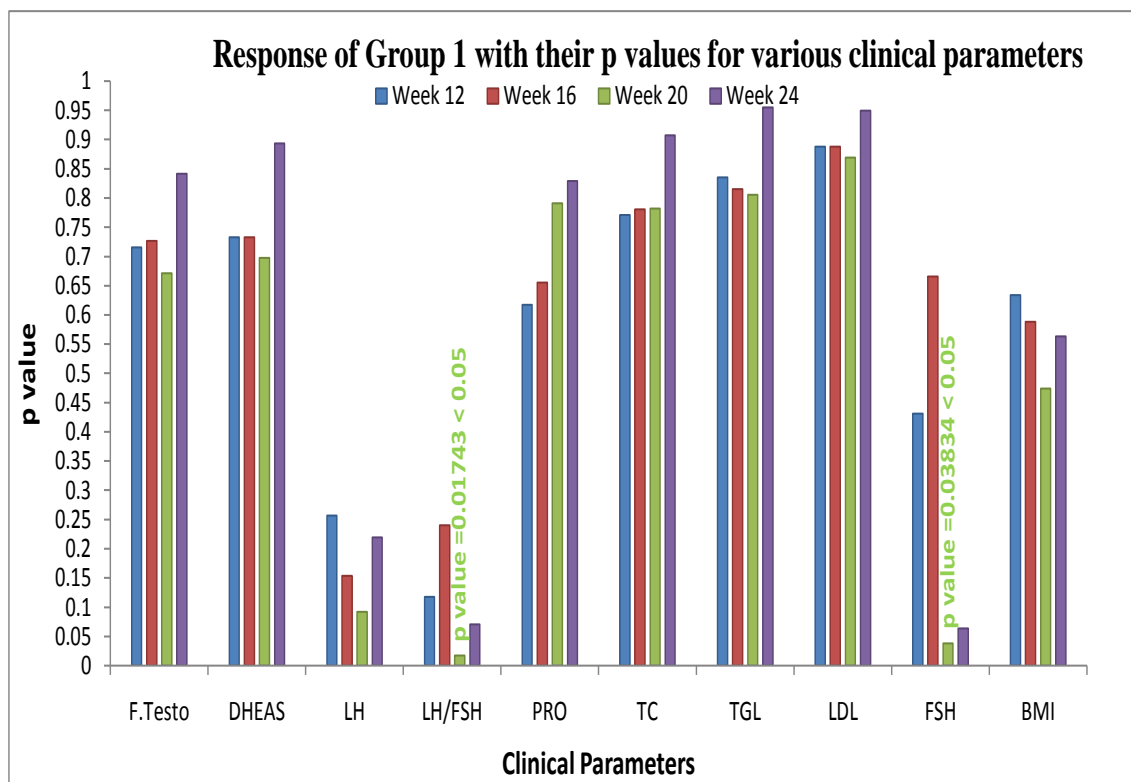


Group 2 subjects had statistically significant from 12 week onwards and this increase of HDL levels after 12, 16, 20 and 24 weeks were statistically more significant with the corresponding p values of i) $0.005502 < 0.01$ ii) $0.00182 < 0.01$ iii) $0.001523 < 0.001$ and iv) $0.004157 < 0.01$ and group 3 had a significant improvement of 3.17% at 16 weeks treatment higher than the other groups 1 and 2. It is observed that Group 3 achieved marked increase of HDL than the Group 1 and Group 2.

Table 40. Response of Group 1 with their p values for various clinical parameters

Parameters / Weeks	4th Week	8th Week	12th Week	16th Week	20th Week	24th Week
F.Testo	0.992221	0.953387	0.715826	0.726729	0.671659	0.841435
DHEAS	0.987707	0.945042	0.732743	0.732743	0.697443	0.893894
LH	0.499624	0.266666	0.256650	0.153671	0.091896	0.219810
LH/FSH	0.989457	0.372393	0.118064	0.240141	0.017413	0.070779
PRO	0.695479	0.590101	0.617507	0.655497	0.790953	0.829273
TC	0.615061	0.667457	0.771491	0.78086	0.78218	0.907766
TGL	0.698012	0.652918	0.835589	0.815704	0.805593	0.955259
LDL	0.748316	0.782517	0.888401	0.888021	0.869431	0.949702
HDL	0.456842	0.606094	0.551975	0.587639	0.666968	0.810471
WT	0.639503	0.387901	0.668356	0.638442	0.529727	0.631920
BMI	0.607807	0.765766	0.633776	0.588604	0.474442	0.563788
BP	0.869128	0.847933	0.823880	0.872273	0.838781	0.773700
FBS	0.530037	0.226233	0.186795	0.214962	0.882341	0.350785
PPBS	0.808728	0.699787	0.985639	0.474514	0.538052	0.632111
F.I	1.000000	0.962219	0.530769	0.552566	0.389316	0.734473
FSH	0.662285	0.969422	0.431206	0.665763	0.038340	0.063492
TSH	0.761180	0.688196	0.857455	0.859915	0.895321	0.761180
T.Testo	0.641182	0.927652	0.263128	0.246134	0.258703	0.696024
Serum Andro	0.998552	0.994218	0.624289	0.607775	0.625778	0.997110

Figure 26. Response of Group 1 with their p values for various clinical parameters

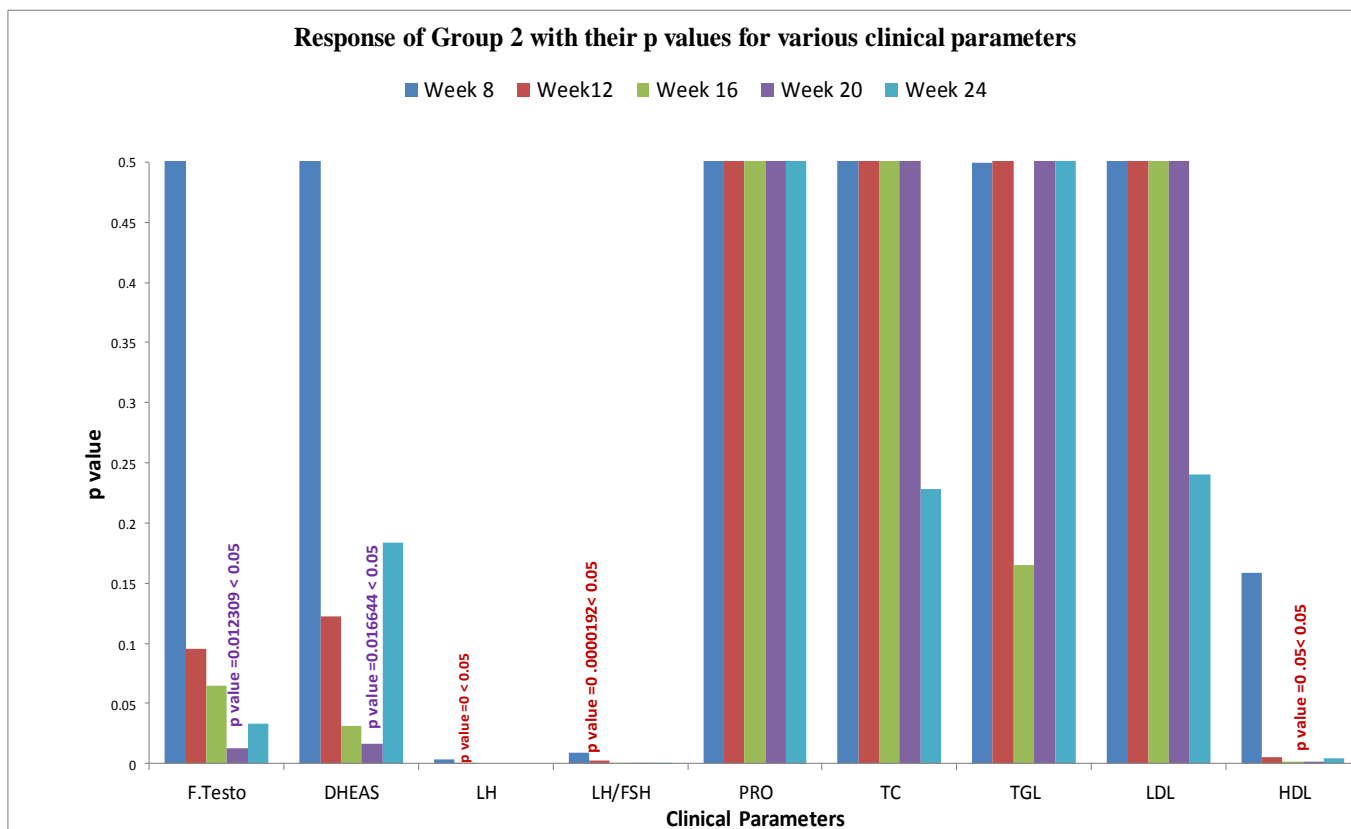


The result of p value after two tailed t-tests for the clinical parameters LH/FSH ratio and FSH are found to be significant with p values(=0.01743 and =0.03834)which is less than 0.05. So, the response of Group 1 shows profound effect on reduction of LH/FSH ratio and FSH values.

Table 41. Response of Group 2 with their p values for various parameters

Parameters / Weeks	4th Week	8th Week	12th Week	16th Week	20th Week	24th Week
F.Testo	0.691412	0.76685	0.095086	0.064771	0.012309	0.033106
DHEAS	0.963057	0.79558	0.122366	0.030895	0.016644	0.183391
LH	0.264354000	0.003728000	0.000015000	0.000000035	0.000000000	0.000000001
LH/FSH	0.962706	0.009073	0.002371	0.000021600	0.000001920	0.000000400
PRO	0.65917	0.93258	0.864548	0.960632	0.921856	0.940318
TC	0.38783	0.861628	0.889956	0.922467	0.582452	0.228513
TGL	0.524396	0.499883	0.789827	0.165288	0.787071	0.57777
LDL	0.475066	0.925478	0.965496	0.940116	0.655423	0.239952
HDL	0.636817	0.158539	0.005502	0.00182	0.001523	0.004157
WT	0.776091	0.591542	0.591542	0.412027	0.246733	0.495219
BMI	0.869218	0.588835	0.412651	0.256057	0.271544	0.300999
BP	0.178396	0.519626	0.097286	0.205549	0.231268	0.225565
FBS	0.700975	0.484494	0.144141	0.321593	0.074449	0.115505
PPBS	0.403964	0.373511	0.638242	0.361414	0.109978	0.065439
F.I	0.993132	0.822581	0.503286	0.416134	0.313996	0.393144
FSH	0.353747	1	0.402621	0.521104	0.362678	0.559258
TSH	0.178019	0.436886	0.070251	0.056141	0.075678	0.120495
T.Testo	0.303379	0.87407	0.194921	0.209327	0.576482	0.513282
Serum Andro	0.994318	0.91705	0.497322	0.545187	0.273956	0.182143

Figure 27. Response of Group 2 with their p values for various clinical parameters

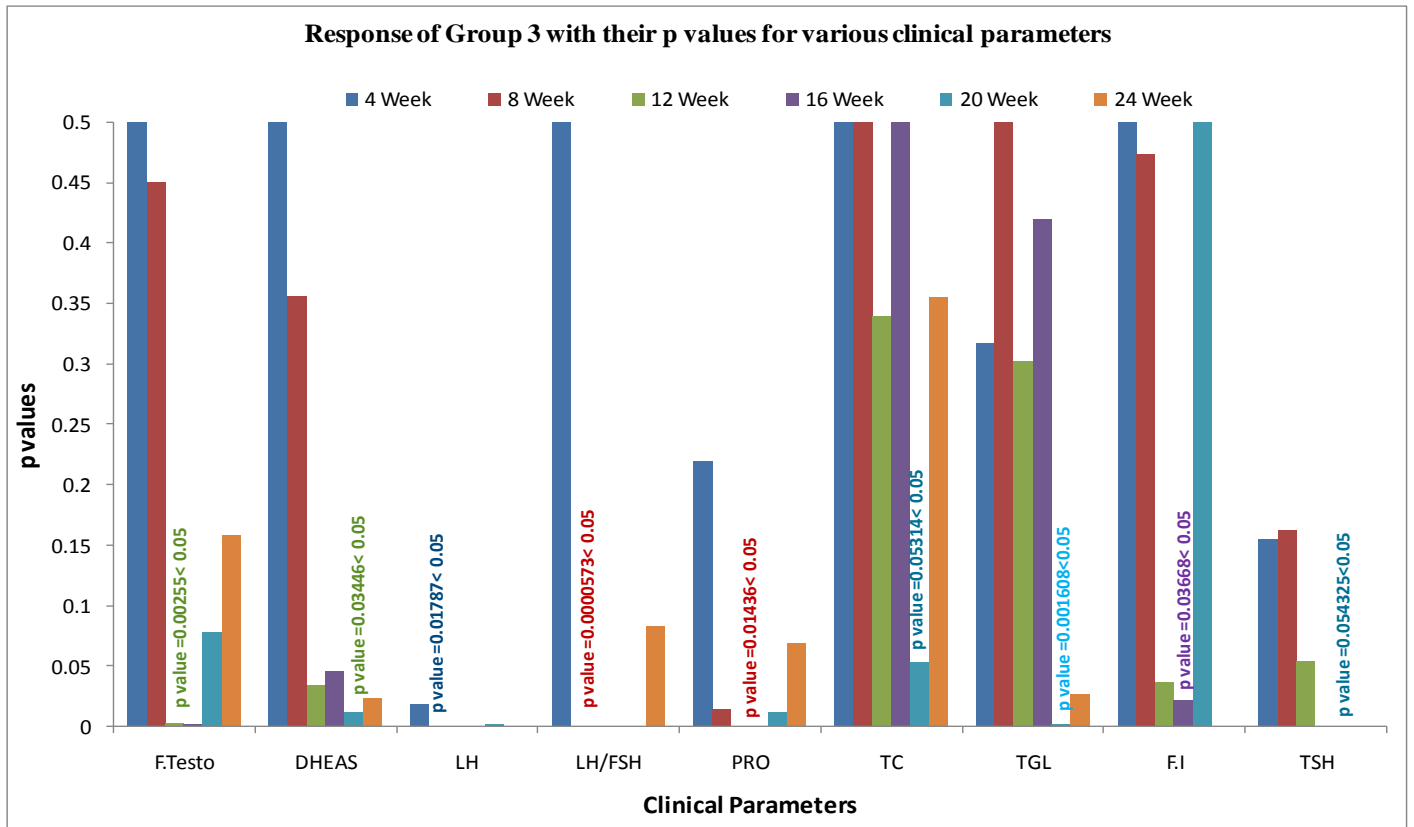


The result of p value after two tailed t-tests for the clinical parameters F.Testo, DHEAS, LH, LH/FSH and HDL are found to be significant with p values ($=0.012309, =0.016644, =0, =0.0000192$ and $=0.05$) which are all less than 0.05. So, the response of Group 2 shows pronouncing effect on F.Testo, DHEAS, LH, LH/FSH ratio, and HDL values.

Table 42. Response of Drug 3 with their p values for various clinical parameters

Parameters/ Weeks	4th Week	8th Week	12th Week	16th Week	20th Week	24th Week
F.Testo	0.535254	0.449837	0.002546	0.001583	0.077263	0.158255
DHEAS	0.67899	0.356797	0.03446	0.045497	0.011193	0.02332
LH	0.01787	0.0000000 156	0.0000000 000000465	0.0000000 0000252	0.001057	0.0000002 93
LH/FSH	0.556073	0.0000573	0.0000001 31	0.0000000 0282	0.00094	0.083772
PRO	0.219497	0.01436	0.000119	0.000135	0.011293	0.068303
TC	0.663699	0.540874	0.338987	0.693362	0.053138	0.355175
TGL	0.316879	0.513371	0.302429	0.420376	0.001608	0.025888
LDL	0.621456	0.415311	0.209659	0.46272	0.13015	0.703133
HDL	0.677932	0.286788	0.115401	0.083178	0.762034	0.812024
WT	0.728857	0.39649	1.671553	0.171306	0.446686	0.705938
BMI	0.730426	0.395014	0.18609	0.11654	0.448112	0.748683
BP	0.258199	0.920065	0.453158	0.475638	0.711113	0.826872
FBS	0.320624	0.3192	0.158457	0.151677	0.704724	0.059300
PPBS	0.58164	0.699123	0.541109	0.767224	0.060207	0.39047
F.I	0.785509	0.473717	0.036675	0.022235	0.523877	0.941334
FSH	0.984572	0.721108	0.729234	0.837296	0.678972	0.347046
TSH	0.154717	0.163003	0.054325	0.783885	0.382364	0.77298
T.Testo	0.979574	0.97549	0.973461	0.639755	0.580906	0.552175
Serum Andro	0.308918	0.982672	0.996268	0.843839	0.696086	0.320649

Figure 28. Response of Group 3 with their p values for various clinical parameters

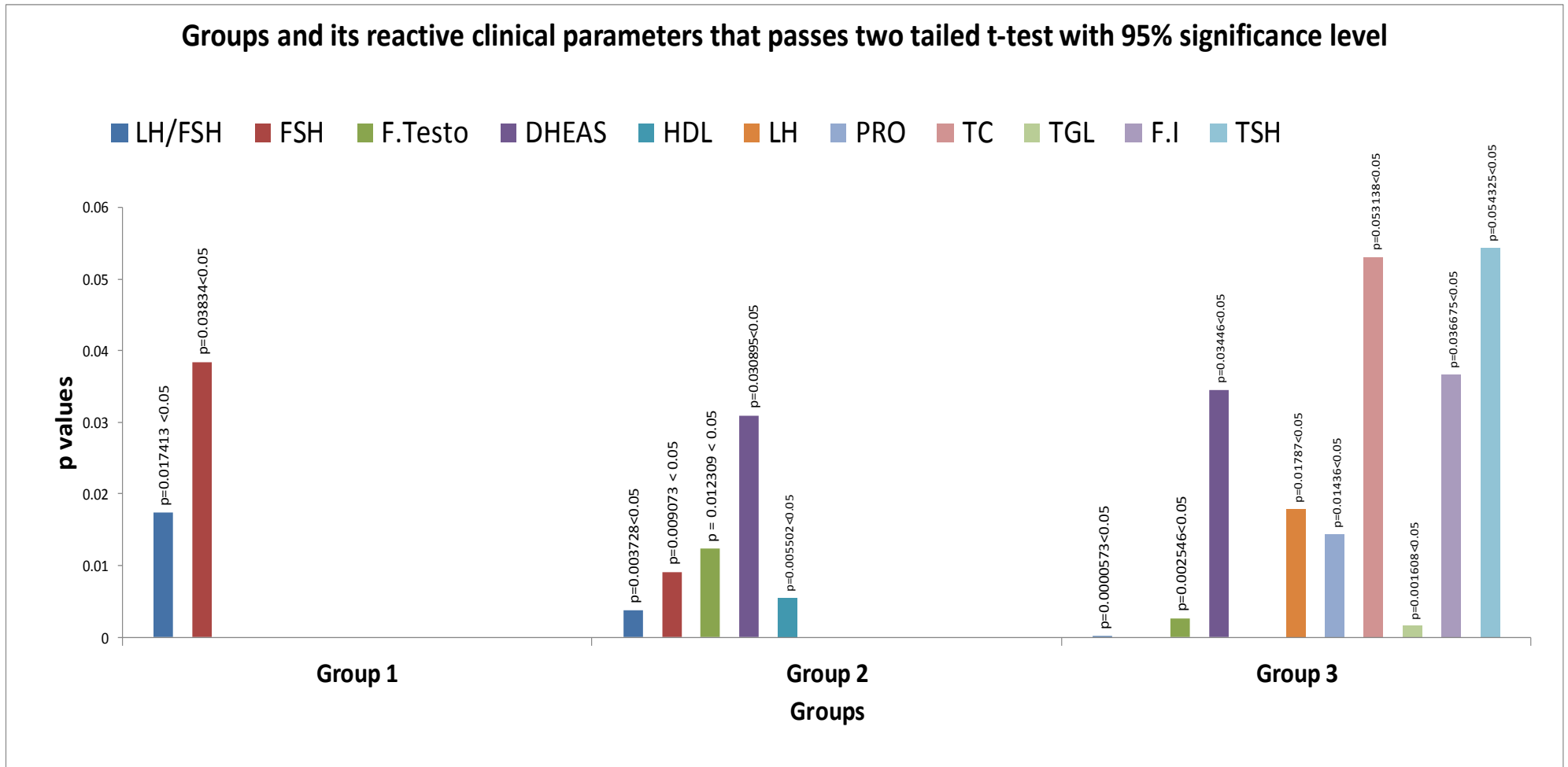


The result of p value after two tailed t-tests for the clinical parameters F.Testo, DHEAS, LH, LH/FSH, PRO, TC, TGL, FI and TSH are found to be statistically significant with p values(=0.00255, =0.03446, =0.01787, =0.0000573, =0.01436, =0.05314, =0.001608, =0.03668 and =0.05433) which are all less than 0.05. So, the response of Group 3 shows most positive response in almost all the clinical parameters such as F.Testo, DHEAS, LH, LH/FSH, PRO, TC, TGL, FI and TSH. Hence the Alternate Hypothesis is proved.

Table 43. Response of Drugs for various clinical parameters over a period of 24 weeks

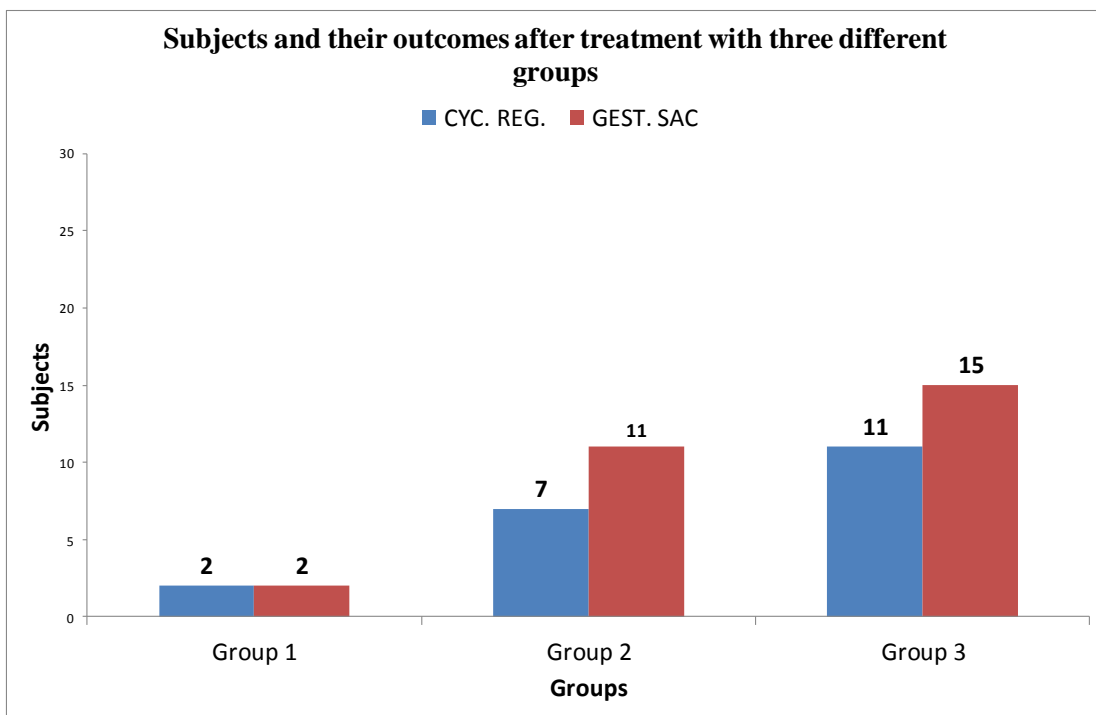
Parameters / Drugs	Drug 1		Drug 2		Drug 3	
	NH	AH	NH	AH	NH	AH
F. Testo	✓			✓ 20 th week		✓ 12 th week
DHEAS	✓			✓ 16 th week		✓ 12 th week
LH	✓			✓ 8 th week		✓ 4 th week
LH/FSH		✓ 20 th week		✓ 8 th week		✓ 8 th week
PRO	✓		✓			✓ 8 th week
TC	✓		✓			✓ 24 th week
TGL	✓		✓			✓ 20 th week
LDL	✓		✓		✓	
HDL	✓			✓ 12 th week	✓	
WT	✓		✓		✓	
BMI	✓		✓		✓	
BP	✓		✓		✓	
FBS	✓		✓		✓	
PPBS	✓		✓		✓	
F.I	✓		✓			✓ 12 th week
FSH		✓ 20 th week	✓		✓	
TSH	✓		✓			✓ 12 th week
T.Testo	✓		✓		✓	
Sevum Andvo	✓		✓		✓	

Figure 29. Groups and its reactive clinical parameters that passes two tailed t-test with 95% significance level



From the Figure 29, it is being inferred that, For Group 3 more number of clinical parameters shows significance response for different age group of populations. The p values for the clinical parameters F.Testo, DHEAS, LH, LH/FSH, PRO, TC, TGL, FBS, PPBS, F.I, TSH are statistically significant ($p < 0.05$) for Group 3 than Group 1 and Group 2.

Figure 30. Subjects and their outcomes after treatment with three different groups



Positive results in treatment were seen for 26 out of 30 patients in Group 3 and maximum positive outcome of 87% was achieved only by Group 3 and Group 2 achieved next level of positive outcome for 18 out of 30 patients with 60% and Group 1 provided positive outcome only for 4 out of 30 patients which is 13.3% only.

DISCUSSION

Polycystic ovarian syndrome is a complex heterogeneous clinical condition characterized by hyperandrogenism with chronic oligo/anovulation. The factors influencing PCOS include genetic predisposition, high levels of insulin in blood, obesity, excessive production of masculine hormones, abnormality in hypothalamic-pituitary-gonadal axis, environmental pollutants, food adulterants and chronic inflammation^[85].

In our study to evaluate the efficacy of MI on 30 PCOS patients compared to placebo (30 patients) and metformin (30 patients) for a period of 24 weeks, at the end of the study period MI treated group results in major reduction in Fasting insulin. Previously similar studies were done by Genazzani *et.al* and Unfer V *et.al*, Martino M zacche *et.al* [60,76].

Our study showed significant reduction in LH from 4th week onwards and reduction in LH/FSH ratio from 8th week onwards in MI group. This was related to the prior studies done by Genazzani *et.al*, Martino M zacchi.*et.al*, Antonio simone lagana *et al*^[76].

Our study also showed significant reduction in prolactin from 8th week onwards in MI treated group compared to placebo and metformin group. Previously similar studies were done by Genazzani *et al*^[76].

Our study showed significant reduction in free testosterone from 12th week onwards in MI treated group and the same reduction was from 20th week only in metformin treated group. This was related the previous studies done by costantino.*et.al*, Nestler.J E *et al.*, Martino M zacchi *et al*^[6,8].

Our study showed significant reduction in DHEA-S from 12th week onwards in MI treated group and the same reduction was from 16th week only in metformin treated group. Prior related studies were done by Costantino *et al*^[8].

Our study showed significant reduction in TC and TGL from 20th week onwards in MI treated group and the similar significance was not found in metformin treated group. This was similar to the previous studies done by Costantino *et al* and Nestler JE *et al*^[6,8].

Our study showed significant reduction in TSH by 12th week in MI treated group and the similar significance was not found in placebo and metformin treated group. There were no previous studies indicating the similar significance.

Our study does not show any significance with respect to the following parameters such as FBS, PPBS, FSH, hormonal parameters such as total testosterone, androstenedione, lipid profile such as LDL and HDL cholesterol.

Regularization of menstrual cycle

In our study 11 out of 13 unmarried women got their cycles regularized after treatment with MI followed by 7 out of 12 women in metformin group and 2 out of 13 in placebo. These were similar to the previous studies done by Genazzani *et al*^[76], who stated that normal menstrual cycles restored with MI were maximum compared to placebo.

Pregnancy Rate

In our study MI group, 15 out of 17 married infertile PCOS women got conceived followed by 11 out of 18 in metformin group and 2 out of 17 in placebo. These were

similar to the previous studies done by Gerli *et al*, who stated that MI has significantly increased the frequency of ovulation and pregnancy rate compared to placebo^[61].

Ovulation Rate

In the present study, in the MI group, total of 26 patients(87%) out of 30 ovulated showing positive results compared to metformin group showing 18 out of 30 patients(60%) showing positive results and placebo group with 4 out of 30 patients (13.3%)with positive results. These were similar to the previous studies done by costantino.et.al, who stated that ovulation restored with MI was maximum compared to placebo^[8].

In a study done by Raffone *et al* comparing the effect of metformin and MI in 120 PCOS patients, out of 60 women 50% restored spontaneous ovulation and spontaneous pregnancy in 11 women and seven drop out because of side effects on treatment with metformin. In MI treated group, out of 60 women 65% restored spontaneous ovulation and spontaneous pregnancy in 18 women. It was suggested that MI treatment seems to be more effective than metformin as first line treatment for restoring normal menstrual cycles in patients with PCOS ^[70].

In this study, the results revealed that MI was found to be better than metformin and placebo in improving the hormonal and metabolic profile with subsequent frequency of ovulation and pregnancy outcomes.

In our study, 5 out of 90 PCOS women showed mild hair growth (hirsutism) on the upper lip which according to Ferriman -gallway visual scale ^[86] comes under the score of <8 which was regarded as normal.

Adverse Drug Reaction

In our study 4 out of 30 patients treated with metformin showed mild GIT disturbances but there were no drop out. MI treated group did not show any adverse events. These were similar to the previous studies done by Carlomagno *et al* who stated that dosage of 4gm/day commonly used in clinics is completely free of side effects.

CONCLUSION

As PCOS is an emerging disorder during adolescence, early intervention is necessary to improve the reproductive health of adolescents and to prevent future complications. It is concluded from the present study that MI (non-hormonal drug) was effective in the treatment of PCOS in terms of regularization of menstrual cycle, induction of ovulation and improving the success rate of pregnancy in infertility cases. It was a safe and effective drug in terms of very minimal or absence of side effects compared to placebo and metformin. The observations made from this study justify the use of MI for the treatment of PCOD. Hence it could be included in the treatment protocol of infertility in the near future. Further research with the ideas of finding out the exact mechanisms including genetic expression for multiple illnesses of the PCOS is required.

LIMITATIONS OF THE STUDY

The present work was limited to the patients in age group of 18-40 years
Genetic expression in PCOS patients was not carried out in this study.

GROUP 1 - CONTROL

Patient ID	Age	MS	Wks	HT	WT	BMI	BP	AC	FBS	PPBS	FBS/PPBS	F.I	I/G	LH	FSH	LH/FSH	TSH	PRO	T.Testo	F.Testo	Serum Andro	DHEAS	TC	TGL	LDL	HDL	USG	PI
1	27	M	0	160	65	25.4	120/80	87	88	110	0.80	13	0.15	12	4.2	2.86	3.14	18.3	0.9	25	2.26	270	190	100.2	120	30	PCO+	
2	30	M	0	164	66	24.5	130/80	87	80	98	0.82	5.2	0.07	10.2	4.6	2.22	3.2	18.2	1	20.14	1.5	214	180	120	140	35	PCO+	
3	25	M	0	158	62	24.8	100/70	87	79	67	1.18	8.6	0.11	10.6	5.4	1.96	3.8	10.3	1.18	10.7	2.1	212	197	94	140	35	PCO+	
4	24	M	0	160	62.3	24.3	100/80	86	67	91	0.74	9.8	0.15	10.8	5.6	1.93	2.3	10	1.18	8.2	2.5	426	197	93.4	124	54.9	PCO+	
5	24	M	0	148	53	24.2	130/80	86	90	123	0.73	9.6	0.10	12.3	6.2	1.98	3	9.6	0.9	9.4	2.4	240	180	90	120	35	PCO+	
6	29	M	0	165	50	18.4	130/80	74	90	72	1.25	10	0.11	12.6	6.4	1.97	3	10.9	0.8	11.8	0.43	263	180	90	120	34	PCO+	
7	26	M	0	168	74	26.2	110/70	90	92	117	0.79	9	0.10	10.7	4.2	2.55	3.4	13	2.3	19	2.26	288	180	100	140	35	PCO+	
8	28	M	0	170	66	22.8	110/70	84	78	103	0.76	9.2	0.12	12.6	6.6	1.91	3.6	12.2	0.95	8.6	2.8	211	171.2	102	106	34	PCO+	
9	26	M	0	159	62	24.5	140/90	87	71	121	0.59	11.6	0.16	10.2	5.4	1.89	7.6	15.6	0.92	20.6	3.2	276	170	140	142	32.3	PCO+	
10	28	M	0	154	58	24.5	120/80	87	82	116	0.71	18.8	0.23	12.6	4.6	2.74	2.4	13.4	0.73	3.6	3	270	226	88	93	38	PCO+	
11	32	M	0	165	49.5	18.2	120/70	74	76	108	0.70	9.6	0.13	12.2	6.2	1.97	1.1	13.4	0.7	8.4	3	268	220	90	100	30	PCO+	
12	30	M	0	165	78	28.7	114/82	96	78	102	0.76	17	0.22	14.4	5.2	2.77	8.1	13.2	1.1	16	1.8	260	220	106	150	32	PCO+	
13	28	UM	0	152	55	23.8	110/70	86	88	110	0.80	9.6	0.11	12.6	6	2.10	3.7	10.4	0.5	7.6	2.1	280	230	148	90	34	PCO+	
14	22	UM	0	164	52.5	19.5	110/80	78	84	100	0.84	7	0.08	12.4	4.2	2.95	3.3	10.6	1.04	4.07	3.8	309	162.1	77.1	85.1	34	PCO+	
15	23	UM	0	151	48	21.1	110/80	80	74	110	0.67	7.6	0.10	8.2	3.4	2.41	2.86	7.6	0.9	5.8	3	262	170.6	150	143	34.3	PCO+	
16	26	UM	0	162	77	29.3	130/80	96	92	112	0.82	10.6	0.12	14.6	5.6	2.61	5.2	18.2	0.95	7.6	4.4	304	234	124	155	45	PCO+	
17	29	UM	0	164	61	22.7	130/90	84	60	77	0.78	3.5	0.06	10	5.2	1.92	2.19	4.9	0.2	8.8	1.77	211.5	180	100	140	35	PCO+	
18	24	UM	0	158	58	23.2	130/80	84	83	95	0.87	15	0.18	7.9	3.4	2.32	1.8	4.9	0.5	8.8	1.7	162	220	90	100	36	PCO+	
19	22	UM	0	172	65	22	90/80	82	78	97	0.80	5.6	0.07	12.4	4.3	2.88	2.6	15.2	0.1	9.6	2.14	200	171.2	103	106	35.4	PCO+	
20	20	UM	0	156	47	19.3	112/80	76	74	94	0.79	9.6	0.13	8.8	3.6	2.44	2.7	13.21	0.8	7.6	2.24	207	170	140	142	30.4	PCO+	
21	22	UM	0	154	60	25.3	120/80	87	94	84	1.12	18	0.19	12.8	4.6	2.78	3.2	11.3	0.9	8.6	2.2	260	190	92	110	30	PCO+	
22	24	UM	0	158	74	29.6	120/80	98	92	78	1.18	15.8	0.17	10.8	4.6	2.35	3.4	10.4	1.04	9	2.2	275	174	96	140	35	PCO+	
23	26	M	0	148	59	26.9	110/70	92	90	120	0.75	8.6	0.10	12.6	5.6	2.25	3.2	7.6	0.7	7.6	2.8	254	220	139	150	32	PCO+	
24	26	M	0	160	66	25.8	100/70	90	78	104	0.75	9.2	0.12	12.6	4.5	2.80	2.4	10.6	0.7	8.2	2.8	270	216	130	160	34	PCO+	
25	26	UM	0	160	65	25.4	130/80	87	88	110	0.80	18	0.20	10.6	5.2	2.04	3.4	11.6	1.2	15.2	2.26	264	180	100.2	120	35	PCO+	
26	23	UM	0	168	74	26.2	110/80	90	92	117	0.79	9	0.10	12.6	4.3	2.93	2.24	13.2	1.4	19.4	2.26	288	180	100	140	35	PCO+	
27	22	UM	0	170	60	20.8	90/70	80	90	120	0.75	10	0.11	12.6	3.2	3.94	3.2	7.6	0.6	10.4	2.26	280	182	94	140	30	PCO+	
28	28	M	0	158	65	26	120/70	90	94	120	0.78	9	0.10	10.6	4.2	2.52	3	13.2	1.2	8.9	2.4	254	170	102	140	30	PCO+	
29	24	M	0	154	68	28.7	110/70	96	82	116	0.71	9	0.11	14.2	6.2	2.29	2.8	12.2	0.7	8.2	2.4	260	180	104	140	28	PCO+	
30	25	M	0	165	50	18.4	120/80	74	90	72	1.25	10	0.11	12.2	5.6	2.18	2.8	12.2	0.7	6.5	2.4	260	180	90	120	35	PCO+	
1	27	M	4	160	66	25.8	120/80	90	86	108	0.80	13	0.15	10	4.2	2.38	3.1	17.6	0.9	25	2.26	270	189	100	121	28	PCO+	
2	30	M	4	164	67	24.9	130/70	87	82	100	0.82	5.2	0.06	10.4	4.2	2.48	3.26	18.2	1	20.14	1.5	214	180	120	140	34	PCO+	
3	25	M	4	158	62	24.8	110/70	87	79	67	1.18	8.6	0.11	10.6	5.6	1.89	3.6	10.2	1.18	10.7	2.1	212	190	92	134	35	PCO+	
4	24	M	4	160	61	23.8	100/80	86	70	90	0.78	9.8	0.14	10.8	5.6	1.93	2.4	10.2	1.18	8.2	2.5	426	196	92.2	122	50	PCO+	
5	24	M	4	148	52	23.7	130/80	86	90	120	0.75	9.6	0.11	12	6.2	1.94	2.8	9.4	0.9	9.4	2.4	240	178	88	122	34	PCO+	

Patient ID	Age	MS	Wks	HT	WT	BMI	BP	AC	FBS	PPBS	FBS/PPBS	F.I	I/G	LH	FSH	LH/FSH	TSH	PRO	T.Testo	F.Testo	Serum Andro	DHEAS	TC	TGL	LDL	HDL	USG	PI
6	29	M	4	165	52	19.1	130/70	76	90	84	1.07	10	0.11	12	6	2.00	2.8	10.8	0.8	11.8	0.43	263	178	86	118	32	PCO+	
7	26	M	4	168	72	25.5	110/80	90	90	117	0.77	9	0.10	10.4	4.6	2.26	3.6	13.2	2.3	19	2.26	288	178	98	138	34	PCO+	
8	28	M	4	170	64	22.1	110/70	82	80	104	0.77	9.2	0.12	10.4	6.6	1.58	3.2	12	0.95	8.6	2.8	210	170	100	103	32	PCO+	
9	26	M	4	159	62	24.5	140/90	87	70	120	0.58	11.6	0.17	10.4	5.2	2.00	7.4	15.4	0.92	20.6	3.2	276	168	138	140	31	PCO+	
10	28	M	4	154	58	24.5	120/70	87	80	114	0.70	18.8	0.24	12.4	4.4	2.82	2.2	12.4	0.73	3.6	3	270	220	84	90	35	PCO+	
11	32	M	4	165	50	18.4	120/70	74	78	110	0.71	9.6	0.12	12.4	6.4	1.94	1.2	12	0.7	8.4	3	268	218	92	108	32	PCO+	
12	30	M	4	165	74	27.2	114/80	92	99	104	0.95	17	0.17	14.2	5.4	2.63	8	13	1.1	16	1.8	260	218	104	148	34	PCO+	
13	28	UM	4	152	54	23.4	114/80	84	90	114	0.79	9.6	0.11	12.6	6.2	2.03	3.6	10.6	0.5	7.6	2.1	280	228	146	88	32	PCO+	
14	22	UM	4	164	50.5	18.8	110/80	76	73	93	0.78	7	0.10	12.6	4	3.15	3.2	10.2	1.04	4.07	3.8	309	160	76	82	32	PCO+	
15	23	UM	4	151	46	20.2	114/82	78	76	100	0.76	7.6	0.10	8.6	3.6	2.39	2.63	7.4	0.9	5.8	3	260	168	148	140	32.2	PCO+	
16	26	UM	4	162	76	29	130/80	96	92	110	0.84	10.6	0.12	14.3	5.4	2.65	5	17.6	0.95	7.6	4.4	304	230	120	156	45	PCO+	
17	29	UM	4	154	60	22.3	130/80	82	64	79	0.81	3.5	0.05	10.6	5.4	1.96	2.18	4.6	0.2	8.8	1.77	211	178	98	138	34	PCO+	
18	24	UM	4	158	56	22.4	130/80	82	110	90	1.22	15	0.14	7.6	3	2.53	1.6	4.8	0.2	8.8	1.7	160	218	88	98	34	PCO+	
19	22	UM	4	172	64	21.6	90/70	82	76	96	0.79	5.6	0.07	12	4.6	2.61		15	0.1	9.6	2.14	200	170	100.2	100.6	34	PCO+	
20	20	UM	4	156	46	18.9	110/80	76	74	94	0.79	9.6	0.13	8.4	3.2	2.63	2.6	13.2	2.8	7.6	2.24	207	168	138	140	30.2	PCO+	
21	22	UM	4	154	58	24.5	120/84	87	96	84	1.14	18	0.19	12.6	4.2	3.00	3	11	0.9	8.6	2.2	260	188	90	106	32	PCO+	
22	24	UM	4	158	70	28	120/70	94	90	82	1.10	15.8	0.18	10.6	4.2	2.52	3.3	9.8	1.04	9	2.25	275	174	94	138	34	PCO+	
23	26	M	4	148	55	25.1	110/70	87	90	104	0.87	8.6	0.10	12	5	2.40	3.1	7.5	0.7	7.6	2.8	254	220	138	148	32	PCO+	
24	26	M	4	160	66	25.8	100/70	90	78	100	0.78	9.2	0.12	12	4	3.00	2	9.4	0.7	8.2	2.8	270	215	128	158	32	PCO+	
25	26	UM	4	160	65	25.4	132/84	87	95	110	0.86	18	0.19	10.8	5	2.16	3.2	11.4	1.2	15	2.2	264	178	98	118	34	PCO+	
26	23	UM	4	168	74	26.2	112/84	90	92	117	0.79	9	0.10	12	4	3.00	2.24	13.2	1.4	19.2	2.26	288	178	98	138	34	PCO+	
27	22	UM	4	170	58	20.1	90/70	78	90	120	0.75	10	0.11	12	3.6	3.33	3.4	7.6	0.6	10.4	2.26	280	180	90	138	28	PCO+	
28	28	M	4	158	64	25.6	120/70	90	84	110	0.76	9	0.11	10	4	2.50	2.8	12.5	1.2	8.9	2.4	254	168	98	138	32	PCO+	
29	24	M	4	154	65	27.4	120/70	92	80	114	0.70	9	0.11	14	6	2.33	2.6	10.6	0.7	8.2	2.4	260	178	102	138	30	PCO+	
30	25	M	4	165	52	19.1	130/90	76	96	80	1.20	10	0.10	12.4	5.2	2.38	2.6	12	0.7	6.5	2.4	260	178	88	118	34	PCO+	
1	27	M	8	160	65	25.4	120/80	87	88	110	0.80	13	0.15	10	6.2	1.61	3.1	17.4	0.9	25	2.2	270	190	98	119	30	PCO+	
2	30	M	8	164	66	24.5	120/82	87	80	98	0.82	5.2	0.07	11.2	5.2	2.15	3.16	17.3	1	20.14	1.6	214	178	118	139	35	PCO+	
3	25	M	8	158	4	24.8	100/70	87	80	97	0.82	8.6	0.11	11	5.8	1.90	3.8	10.3	1.1	10.6	2.1	212	197	94	140	34	PCO+	
4	24	M	8	160	62.3	24.3	100/80	86	70	90	0.78	9.8	0.14	10.4	4.3	2.42	2.3	10	1.18	8.2	2.5	424	196	92	120	52	PCO+	
5	24	M	8	148	53	24.2	120/80	86	90	120	0.75	9.4	0.10	10	5.4	1.85	3	9.6	0.9	9.2	2.6	240	178	88	122	34	PCO+	
6	29	M	8	165	52	19.1	130/80	76	90	82	1.10	9.8	0.11	12.4	6.2	2.00	2.8	10.8	0.8	11.6	0.43	260	178	88	118	32	PCO+	
7	26	M	8	168	74	26.2	120/80	90	90	110	0.82	9	0.10	10	4.2	2.38	3.4	13	2.3	18.6	2.26	288	178	98	140	33	PCO+	
8	28	M	8	170	64	22.1	110/80	82	78	100	0.78	9.2	0.12	12.4	6.4	1.94	3.4	12	0.95	8.4	2.7	210	168	102	106	33	PCO+	
9	26	M	8	159	62	24.5	140/80	87	80	118	0.68	11.6	0.15	10.4	5.4	1.93	7.4	15	0.92	20.6	3.2	276	168	138	140	32.2	PCO+	
10	28	M	8	154	58	24.5	120/70	87	82	100	0.82	18.8	0.23	12.6	4.6	2.74	2.2	12.4	0.73	3.6	3	270	218	82	92	36	PCO+	
11	32	M	8	165	49.5	18.2	130/80	74	82	110	0.75	9.6	0.12	12.2	6.2	1.97	1.1	12.4	0.7	8.4	3.1	268	218	92	104	32	PCO+	

Patient ID	Age	MS	Wks	HT	WT	BMI	BP	AC	FBS	PPBS	FBS/PPBS	F.I	I/G	LH	FSH	LH/FSH	TSH	PRO	T.Testo	F.Testo	Serum Andro	DHEAS	TC	TGL	LDL	HDL	USG	PI
12	30	M	8	165	74	27.2	110/80	92	98	84	1.17	17	0.17	14.4	5.6	2.57	7.8	13	1.1	16	1.8	258	220	104	150	34	PCO+	
13	28	UM	8	152	55	23.8	110/70	86	96	110	0.87	9.6	0.10	12.4	6	2.07	3.6	9.6	0.5	7.6	2.1	80	228	146	88	32	PCO+	
14	22	UM	8	164	52	19.3	120/80	76	84	93	0.90	7	0.08	12.4	4.6	2.70	3.3	10.4	1.04	4.07	3.8	308	158	76	82	32	PCO+	
15	23	UM	8	151	48	21.1	114/82	80	74	100	0.74	7.6	0.10	8.2	3	2.73	2.63	7.4	0.9	5.2	3	260	168	146	140	32.2	PCO+	
16	26	UM	8	162	77	29.3	114/82	96	92	110	0.84	10.6	0.12	14.2	5.6	2.54	5	17.4	0.95	7.6	4.4	304	232	120	154	45	PCO+	
17	29	UM	8	164	60	22.3	130/80	82	69	84	0.82	3.5	0.05	10.2	4.6	2.22	2.16	4.6	0.2	8.8	1.7	211	178	98	138	34	PCO+	
18	24	UM	8	158	58	23.2	132/84	84	110	90	1.22	15	0.14	7.2	3.3	2.18	1.6	4.6	0.2	8.7	1.7	162	218	88	98	34	PCO+	
19	22	UM	8	172	64	21.6	90/70	82	76	96	0.79	5.6	0.07	12.4	4.2	2.95		14.8	0.1	9.6	2.14	198	168	100.2	106	34	PCO+	
20	20	UM	8	156	46	18.9	112/82	76	74	92	0.80	9.6	0.13	8.6	3	2.87	2.4	13	0.8	7.6	2.24	207	168	138	138	32	PCO+	
21	22	UM	8	154	58	24.5	120/84	87	96	84	1.14	18	0.19	10.6	4.8	2.21	3.1	10.8	0.9	8.4	2.2	260	186	88	106	30	PCO+	
22	24	UM	8	158	70	28	120/80	94	90	84	1.07	15.8	0.18	8.4	3.2	2.63	3.2	9.8	1.04	9	2.25	275	174	94	138	34	PCO+	
23	26	M	8	148	54	24.7	120/70	87	90	110	0.82	8.6	0.10	10.6	6.2	1.71	3	7	0.7	7.6	2.8	250	218	138	148	32	PCO+	
24	26	M	8	160	65	25.4	110/70	87	80	110	0.73	9.2	0.12	10	5.6	1.79	2.3	10.6	0.8	8.2	2.8	265	215	125	158	32	PCO+	
25	26	UM	8	160	65	25.4	130/80	87	88	110	0.80	17	0.19	12.6	6.2	2.03	3	10.2	1.2	15	2.2	264	178	98	118	34	PCO+	
26	23	UM	8	168	74	26.2	112/84	90	92	110	0.84	9	0.10	12.4	4	3.10	2.2	13	1.4	19.2	2.2	286	178	96	138	34	PCO+	
27	22	UM	8	170	60	20.8	90/70	80	90	100	0.90	10	0.11	11.8	3.8	3.11	3.2	7.4	0.6	10.4	2.2	280	180	90	138	28	PCO+	
28	28	M	8	158	65	26	120/70	90	92	110	0.84	9	0.10	10	4.2	2.38	2.8	12.5	1.2	8.9	2.4	256	168	98	138	32	PCO+	
29	24	M	8	154	68	28.7	110/70	96	82	100	0.82	9	0.11	13.8	5.8	2.38	2.5	10.6	0.7	8.2	2.4	260	178	102	138	32	PCO+	
30	25	M	8	165	52	19.1	130/80	76	95	110	0.86	10	0.11	12	5	2.40	2.6	12.2	0.7	6.5	2.4	258	178	88	118	34	PCO+	
1	27	M	12	160	67	26.2	120/70	90	86	108	0.80	14	0.16	12	4.2	2.86	3	18.3	0.9	24	2.26	268	189	100	128	28	PCO+	
2	30	M	12	164	66	24.5	120/70	87	90	100	0.90	5.2	0.06	10.4	4.2	2.48	3.2	17.3	1	19.14	1.6	213	180	120	140	34	PCO+	
3	25	M	12	158	62	24.8	110/70	87	80	110	0.73	8.6	0.11	10.2	5.4	1.89	3.8	10.2	1.18	10.6	2.1	214	190	90	140	35	PCO+	
4	24	M	12	160	63	24.6	110/80	87	72	94	0.77	9.8	0.14	10	5.2	1.92	2	10.4	1.1	8	2.5	424	196	93	120	52	PCO+	
5	24	M	12	148	54	24.7	120/80	87	90	123	0.73	9.4	0.10	12	6.2	1.94	2.8	9.4	1	9.2	2.6	236	180	92	120	36	PCO+	
6	29	M	12	165	50	18.4	120/80	74	90	80	1.13	9.6	0.11	12.6	6.4	1.97	3	10.9	0.7	11.6	0.4	260	180	90	120	34	PCO+	
7	26	M	12	168	74	26.2	120/80	90	94	112	0.84	8.8	0.09	12.4	6.4	1.94	3.4	13.2	1.9	18.6	2.2	280	180	100	138	34	PCO+	
8	28	M	12	170	66	22.8	110/80	84	78	103	0.76	9.4	0.12	12.6	6.6	1.91	3.2	12	1	8.4	2.6	206	170	102.6	108	32	PCO+	
9	26	M	12	159	60	23.7	130/80	86	90	110	0.82	11.4	0.13	10.2	5.2	1.96	7.4	14.8	0.9	20	3.1	274	170	140	140	32.2	PCO+	
10	28	M	12	154	58	24.5	120/80	87	82	100	0.82	18.6	0.23	12	6	2.00	2.4	12.6	0.4	3.8	3.2	266	220	82	90	36	PCO+	
11	32	M	12	165	49.5	18.2	120/80	74	76	108	0.70	9.4	0.12	12	6.2	1.94	1.1	13.4	0.6	8.2	3.1	264	220	90	104	30	PCO+	
12	30	M	12	165	78	28.7	110/80	96	90	73	1.23	16	0.18	14	5.8	2.41	7.8	12.8	1	14.2	1.6	258	218	104	148	30	PCO+	
13	28	UM	12	152	55	23.8	114/82	86	96	110	0.87	9.4	0.10	12.2	6.2	1.97	3.7	9.6	0.6	7.4	2	278	230	148	90	34	PCO+	
14	22	UM	12	164	52	19.3	120/80	76	82	96	0.85	6.8	0.08	12.2	4.2	2.90	3.2	10.4	1	4.07	3.6	300	160.2	77	84	30	PCO+	
15	23	UM	12	151	48	21.1	110/82	80	74	100	0.74	7.4	0.10	8.2	3	2.73	2.4	7.6	0.6	5.6	2.8	256	170.6	146	140	30.2	PCO+	
16	26	UM	12	162	76	29	130/82	96	92	112	0.82	9.8	0.11	14	7.2	1.94	5.1	17.4	0.8	7.4	4.2	3.2	230	120	150	44	PCO+	
17	29	UM	12	164	60	22.3	130/80	82	69	86	0.80	3.4	0.05	10.2	4.2	2.43	2.16	4.6	0.1	8.6	1.63	200	180	96	136	34	PCO+	

Patient ID	Age	MS	Wks	HT	WT	BMI	BP	AC	FBS	PPBS	FBS/PPBS	F.I	I/G	LH	FSH	LH/FSH	TSH	PRO	T.Testo	F.Testo	Serum Andro	DHEAS	TC	TGL	LDL	HDL	USG	PI
18	24	UM	12	158	58	23.2	134/82	84	93	95	0.98	12	0.13	7	3	2.33	1.6	4.6	0.1	8.6	1.6	160	220	86	100	36	PCO+	
19	22	UM	12	172	64	21.6	90/74	82	82	92	0.89	5.4	0.07	12	4.3	2.79	2.4	15	0.1	9.4	2.1	198	168	103	104	34	PCO+	
20	20	UM	12	156	46	18.9	110/80	76	82	90	0.91	9.4	0.11	8.8	3.6	2.44	2.6	12.4	0.6	7.4	2.3	204	170	138	138	28.6	PCO+	
21	22	UM	12	154	56	23.6	120/80	86	90	100	0.90	15	0.17	9.6	4.6	2.09	3.1	9.8	0.8	8.2	2	255	190	90	110	32	PCO+	
22	24	UM	12	158	68	27.2	120/70	92	90	84	1.07	13.3	0.15	8.6	3	2.87	3.4	8.6	1	8	2.2	270	170	96	140	32	PCO+	
23	26	M	12	148	50	22.8	120/70	84	98	110	0.89	8.4	0.09	8.4	7.6	1.11	3	7.6	0.6	6.5	2.6	246	220	139	150	34	PCO+	
24	26	M	12	160	64	25	90/70	87	82	98	0.84	8	0.10	8.6	4.2	2.05	2	9.4	0.8	7.6	2.8	265	214	130	156	32	PCO+	
25	26	UM	12	160	64	25	120/80	87	90	110	0.82	17	0.19	12.6	6	2.10	3.2	10.4	1	14	2.2	260	180	100	120	35	PCO+	
26	23	UM	12	168	73	25.9	110/80	90	90	110	0.82	8	0.09	12.8	6.2	2.06	2.2	12.8	1	18.2	2.2	280	180	98	140	35	PCO+	
27	22	UM	12	170	58	20.1	100/70	78	90	110	0.82	9.8	0.11	12	3.8	3.16	3.2	7	0.7	9.8	2.2	278	182	94	140	30	PCO+	
28	28	M	12	158	64	25.6	110/70	90	84	120	0.70	8.4	0.10	10.6	4	2.65	3	13	1	8	2	250	170	102	140	30	PCO+	
29	24	M	12	154	68	28.7	110/70	96	84	110	0.76	8.8	0.10	14	6.2	2.26	2.8	12.2	0.4	8	2	256	180	104	140	32	PCO+	
30	25	M	12	165	50	18.4	130/80	74	90	112	0.80	8.2	0.09	11.8	6.2	1.90	2	12.2	0.6	6.2	2	256	178	90	120	35	PCO+	
1	27	M	16	160	65	25.4	120/70	87	86	110	0.78	14	0.16	12	4.2	2.86	3.1	18.2	0.9	24	2.26	268	190	100.2	121	30	PCO+	
2	30	M	16	164	67	24.9	120/70	87	88	106	0.83	5.2	0.06	10.2	5.2	1.96	3.2	18.2	1	19.14	1.6	213	178	120	140	35	PCO+	
3	25	M	16	158	62	24.8	110/70	87	80	97	0.82	8.6	0.11	10.2	5	2.04	3.6	10.3	1.16	10.6	2.1	214	190	94.8	140	35	PCO+	
4	24	M	16	160	61	23.8	110/80	86	70	90	0.78	9.8	0.14	10.2	4.2	2.43	2.3	9.6	1.1	8	2.4	424	197	94	122	50	PCO+	
5	24	M	16	148	53	24.2	110/80	86	90	120	0.75	9.4	0.10	12	6	2.00	3	9.2	1	9.2	2.6	236	178	90	118	36	PCO+	
6	29	M	16	165	52	19.1	120/80	76	94	84	1.12	10	0.11	12	5.6	2.14	2.8	10	0.7	11.8	0.4	260	176	88	120	34	PCO+	
7	26	M	16	168	72	25.5	120/80	90	90	117	0.77	8.8	0.10	10	6	1.67	3.6	12.6	1.9	18.6	2.2	280	176	96	140	33	PCO+	
8	28	M	16	170	66	22.8	110/80	84	80	104	0.77	9.4	0.12	12.4	6	2.07	3.6	12.2	1	8.4	2.6	206	170	100.2	106	32	PCO+	
9	26	M	16	159	62	24.5	130/80	87	80	120	0.67	11.4	0.14	10	5	2.00	7.4	14.8	0.9	20	3.1	274	172	142	138	30.3	PCO+	
10	28	M	16	157	54	22.8	120/80	84	82	116	0.71	18.6	0.23	12.4	6.2	2.00	2.4	12.6	0.4	3.8	3.2	266	220	84	92	35	PCO+	
11	32	M	16	165	49	18	120/80	74	76	108	0.70	9.4	0.12	12.4	6	2.07	1.1	13.4	0.6	8.2	3.1	264	218	88	108	30	PCO+	
12	30	M	16	165	78	28.7	120/80	96	99	104	0.95	16	0.16	14.4	5	2.88	8	13	1	14	1.6	258	218	108	150	32	PCO+	
13	28	UM	16	152	55	23.8	110/80	86	90	114	0.79	9.4	0.10	12	6	2.00	3.7	10	0.6	7.4	2	278	228	148	92	34	PCO+	
14	22	UM	16	164	52	19.3	120/80	76	84	92	0.91	6.8	0.08	12.4	4.6	2.70	3.3	10.6	1	4.07	3.6	300	160.2	77	86	34	PCO+	
15	23	UM	16	151	48	21.1	110/80	80	76	110	0.69	7.4	0.10	8	3.2	2.50	2.4	7.8	0.6	5.6	2.8	256	170.4	146	142	30.2	PCO+	
16	26	UM	16	162	76	29	130/80	96	90	110	0.82	9.8	0.11	14	7.2	1.94	5.2	17.4	0.8	7.4	4.2	302	232	126	150	43	PCO+	
17	29	UM	16	164	61	22.7	130/84	84	69	84	0.82	3.4	0.05	10.6	4.6	2.30	2.18	4.6	0.1	8.6	1.6	200	180	100	136	35	PCO+	
18	24	UM	16	158	58	23.2	130/80	84	100	90	1.11	12	0.12	7.6	3	2.53	1.8	4.9	0.1	8.6	1.6	160	218	90	98	34	PCO+	
19	22	UM	16	172	65	22	90/74	82	76	84	0.90	5.4	0.07	12.4	4.3	2.88		15	0.1	9.4	2.1	198	170.2	103	104	35	PCO+	
20	20	UM	16	156	47	19.3	110/80	76	76	94	0.81	9.4	0.12	8.4	3.2	2.63	2.4	13	0.6	7.4	2.3	204	172	140	140	28.6	PCO+	
21	22	UM	16	154	56	23.6	120/80	86	92	110	0.84	15	0.16	9.6	4.6	2.09	3	10.8	0.8	8.2	2	255	190	88	110	32	PCO+	
22	24	UM	16	158	67	26.8	120/70	92	92	82	1.12	13.8	0.15	7.4	3.6	2.06	3.4	8.6	1	8	2.2	270	170	94	140	32	PCO+	
23	26	M	16	148	50	22.8	110/70	84	92	123	0.75	8.4	0.09	8.2	9.6	0.85	2.8	7.5	0.6	6.5	2.6	246	219	138	148	34	PCO+	

Patient ID	Age	MS	Wks	HT	WT	BMI	BP	AC	FBS	PPBS	FBS/PPBS	F.I	I/G	LH	FSH	LH/FSH	TSH	PRO	T.Testo	F.Testo	Serum Andro	DHEAS	TC	TGL	LDL	HDL	USG	PI
24	26	M	16	160	64	25	100/70	87	90	106	0.85	8	0.09	7.6	4	1.90	2.3	9.4	0.7	7.6	2.8	265	216	128	160	34	PCO+	
25	26	UM	16	160	64	25	120/80	87	84	100	0.84	17	0.20	10.8	5.2	2.08	3.4	11.2	1	14	2.2	260	178	98	118	34	PCO+	
26	23	UM	16	168	73	25.9	110/80	90	92	117	0.79	8	0.09	12.8	6	2.13	2.2	12.8	1	18.2	2.2	280	178	96	140	34	PCO+	
27	22	UM	16	170	60	20.8	100/70	80	90	124	0.73	9.8	0.11	12.6	3	4.20	3	7.4	0.7	9.8	2.2	278	180	90	138	32	PCO+	
28	28	M	16	158	64	25.6	110/70	90	90	120	0.75	8.4	0.09	10.2	4.6	2.22	2.8	12.2	1	8.6	2	250	168	98	138	32	PCO+	
29	24	M	16	154	68	28.7	112/82	96	86	100	0.86	8.8	0.10	14.2	6.4	2.22	2.6	12	0.4	8	2	256	178	103	138	30	PCO+	
30	25	M	16	165	50	18.4	120/82	74	90	110	0.82	8.2	0.09	12	4.8	2.50	2.8	12	0.6	6.2	2	256	180	88	121	34	PCO+	
1	27	M	20	160	66	25.8	120/70	90	84	108	0.78	14	0.17	10	5.6	1.79	3.1	18.3	0.9	24	2.25	268	189	98	119	30	PCO+	
2	30	M	20	164	66	24.5	120/70	87	102	110	0.93	5.2	0.05	10.6	4.2	2.52	3.16	18.2	1	19.14	1.5	213	180	120	140	35	PCO+	
3	25	M	20	158	62	24.8	110/70	87	18	110	0.16	8.6	0.48	10.6	5.2	2.04	3.16	10.3	1.16	10.6	2.1	212	190	94	134	35	PCO+	
4	24	M	20	160	61	23.8	100/80	86	64	90	0.71	9.8	0.15	10.2	5.6	1.82	2.3	10.4	1.1	8	2.5	424	196	93	124	52	PCO+	
5	24	M	20	148	54	24.7	110/80	87	90	110	0.82	9.6	0.11	12	6	2.00	3	9.4	0.9	9.4	2.4	236	178	90	120	35	PCO+	
6	29	M	20	165	50	18.4	120/80	74	90	80	1.13	9.8	0.11	12.6	5.6	2.25	2.8	10.9	0.7	11.8	0.4	263	176	88	118	32	PCO+	
7	26	M	20	168	72	25.5	120/80	90	94	112	0.84	9	0.10	10.4	4.2	2.48	3.6	12.6	1.9	18.6	2.2	280	176	96	140	35	PCO+	
8	28	M	20	170	65	22.5	110/80	84	80	100	0.80	9.4	0.12	12	6	2.00	3.4	12.4	1	8.4	2.6	206	168	98	106	32	PCO+	
9	26	M	20	159	62	24.5	130/80	87	80	110	0.73	11.6	0.15	10.2	5.2	1.96	7.6	15	0.9	20	3.1	274	172	142	138	30.3	PCO+	
10	28	M	20	154	54	22.8	120/80	84	80	116	0.69	18.6	0.23	12.4	6.2	2.00	2.2	13.4	0.4	3.8	3.2	266	226	84	92	35	PCO+	
11	32	M	20	165	50	18.4	120/80	74	78	110	0.71	9.6	0.12	12.4	6.4	1.94	1.4	13.4	0.6	8.2	3	264	216	90	108	30	PCO+	
12	30	M	20	165	78	28.7	120/80	96	78	102	0.76	16	0.21	14	5	2.80	8	13.2	1	14	1.6	258	222	106	152	34	PCO+	
13	28	UM	20	152	55	23.8	110/80	86	88	114	0.77	9.4	0.11	12.6	6.2	2.03	3.7	10.6	0.6	7.4	2	278	226	148	92	32	PCO+	
14	22	UM	20	164	52	19.3	120/80	76	84	92	0.91	6.8	0.08	12.4	4.6	2.70	3	11.2	1	4.07	3.6	300	160.2	76	86	34	PCO+	
15	23	UM	20	151	46	20.2	110/80	78	74	100	0.74	7.4	0.10	8.2	3.4	2.41	2.86	7.6	0.6	5.6	2.8	256	168	148	142	34	PCO+	
16	26	UM	20	162	76	29	120/80	96	90	110	0.82	9.8	0.11	14.3	7.3	1.96	5.1	17.2	0.8	7.4	4.2	302	234	126	154	44	PCO+	
17	29	UM	20	164	61	22.7	130/84	84	64	82	0.78	3.4	0.05	10.6	5.4	1.96	2	4.9	0.1	8.6	1.6	200	178	98	140	35	PCO+	
18	24	UM	20	158	56	22.4	130/80	82	84	96	0.88	12	0.14	7.6	3	2.53	1.8	4.9	0.1	8.6	1.6	160	216	88	96	34	PCO+	
19	22	UM	20	172	65	22	100/70	82	82	92	0.89	5.4	0.07	12	5.2	2.31		15	0.1	9.4	2.1	198	170.2	103	104	35	PCO+	
20	20	UM	20	156	47	19.3	100/80	76	76	94	0.81	9.4	0.12	8.2	3.6	2.28	2.7	12.4	0.6	7.4	2.3	204	172	140	142	30.2	PCO+	
21	22	UM	20	154	55	23.2	120/82	81	90	100	0.90	12	0.13	7.6	8.4	0.90	3	11.2	0.9	7.6	2.2	250	190	92	106	30		Cyc.Reg
22	24	UM	20	158	65	26	120/70	90	90	100	0.90	10.6	0.12	6.2	12.4	0.50	3	8.4	1	7	2.25	268	174	94	138	34		Cyc.Reg
23	26	M	20	148	48	21.9	120/70	82	90	120	0.75	8.6	0.10	8.2	10.6	0.77	3.1	7.6	0.7	5.4	2.8	240	220	138	150	34	GES.SAC	
24	26	M	20	160	62	24.2	100/70	86	90	110	0.82	6.2	0.07	6.5	10.6	0.61	2.4	9.4	0.7	7	2.8	260	216	128	160	34	GES.SAC	
25	26	UM	20	160	65	25.4	120/80	87	82	114	0.72	17	0.21	10.6	5	2.12	3.4	11.4	1	14	2.2	260	178	98	118	34	PCO+	
26	23	UM	20	168	73	25.9	110/80	90	92	117	0.79	8	0.09	12.4	6	2.07	2.24	13	1	18.2	2.2	280	178	96	138	34	PCO+	
27	22	UM	20	170	60	20.8	100/70	80	90	124	0.73	9.8	0.11	12.6	3.2	3.94	3.2	7.6	0.7	9.8	2.2	278	180	90	138	30	PCO+	
28	28	M	20	158	65	26	110/70	90	90	120	0.75	8.4	0.09	9.8	4.2	2.33	2.8	12.2	1	8.6	2	250	168	102	136	30	PCO+	
29	24	M	20	154	67	28.3	110/80	94	90	110	0.82	8.8	0.10	14.2	6.2	2.29	2.6	12	0.4	8	2	256	178	102	138	30	PCO+	

GROUP 2 - METFORMIN

Patient ID	Age	MS	Wks	HT	WT	BMI	BP	AC	FBS	PPBS	FBS/PPBS	F.I	I/G	LH	FSH	LH/FSH	TSH	PRO	T.Testo	F.Testo	Serum Andro	DHEAS	TC	TGL	LDL	HDL	USG	PI
1	29	M	0	164	69	25.7	110/90	90	84	101	0.83	15	0.18	14.2	5.2	2.73	2.4	12.4	1.08	10.86	2.3	286	180	104	140	28	PCO+	
2	27	M	0	166	67	24.3	150/110	86	78	71	1.10	8	0.10	12.4	6.4	1.94	3.14	12.6	0.9	6.8	4.46	318	190	100	120	40	PCO+	
3	25	M	0	162	80	30.5	110/70	99	89	126	0.71	3.9	0.04	14.2	5.2	2.73	2.4	14.6	1.1	7.6	3.6	273	220	92	98	32	PCO+	
4	29	M	0	156	64	26.3	140/100	90	90	110	0.82	15.6	0.17	12.4	4.2	2.95	4.4	10.6	0.1	9	2.6	302	210	90	110	30	PCO+	
5	26	M	0	164	49	18.2	120/80	74	90	76	1.18	8.3	0.09	12.6	6.4	1.97	4	10.1	0.8	11	0.4	282	200	94	100	32	PCO+	
6	24	M	0	160	58	22.7	120/70	84	96	84	1.14	6.2	0.06	12.4	6	2.07	3.4	9.6	0.9	9.3	2.26	250	190	102	92	30	PCO+	
7	24	M	0	164	63	23.4	120/80	84	89	126	0.71	4.2	0.05	10.6	4.6	2.30	2.44	10.3	1.12	7.2	3.8	273	210	102	92	30	PCO+	
8	26	M	0	156	50	20.5	140/90	80	80	76	1.05	17.2	0.22	10.4	5.2	2.00	2.76	12.2	0.8	8.6	2.24	207	214	100	94	32	PCO+	
9	23	M	0	164	61	22.7	90/70	84	60	77	0.78	3.5	0.06	12.2	4.6	2.65	2.2	10.4	0.7	12.2	1.8	212.3	220	92	98	32	PCO+	
10	24	M	0	166	52	18.9	140/90	76	76	108	0.70	9.2	0.12	10.2	4.5	2.27	7.1	13.4	0.7	7.2	3.1	268	210	102	72	32	PCO+	
11	19	UM	0	152	66	28.6	100/70	96	88	110	0.80	17	0.19	12.6	6.2	2.03	4.2	10	1.1	10.6	2.1	280	210	98	102	32	PCO+	
12	22	UM	0	152	40	17.3	100/70	72	74	110	0.67	7.6	0.10	10.8	5.2	2.08	2.86	9.2	0.9	7.6	3	262	210	90	110	30	PCO+	
13	22	UM	0	162	77	29.3	120/80	98	92	112	0.82	8.2	0.09	10.3	5.6	1.84	5.1	5	0.9	6.2	4.2	428	200	92	100	30	PCO+	
14	20	UM	0	150	58	25.8	100/70	90	82	112	0.73	10.1	0.12	14.2	5.2	2.73	3.1	13.2	0.7	8.2	2.1	263	170	102	140	30	PCO+	
15	20	UM	0	160	61	23.8	110/70	86	70	91	0.77	7.6	0.11	16.2	7.6	2.13	3.2	10.6	1.04	9.4	2.35	355	200	100	94	32	PCO+	
16	24	UM	0	154	63	26.6	90/70	92	96	84	1.14	18	0.19	12.8	4.6	2.78	4	10.3	0.9	8.9	2.26	302	198	92	98	30	PCO+	
17	30	M	0	164	60	22.3	90/70	82	90	76	1.18	6.5	0.07	12.4	6.5	1.91	4	9.6	1.2	10.3	2.4	270	190	90	100	30	PCO+	
18	28	M	0	158	62	24.8	150/100	87	96	84	1.14	10.3	0.11	14.2	4.2	3.38	3.8	9.2	0.8	8.6	2.8	245	190	100	90	30	PCO+	
19	24	M	0	160	62	24.2	100/70	86	90	76	1.18	6.5	0.07	12.2	6.3	1.94	3.2	10.3	0.9	10.6	2.8	243	180	92	100	30	PCO+	
20	20	UM	0	160	58	22.7	120/80	84	96	84	1.14	7.5	0.08	14.2	6.2	2.29	3.4	10.6	1.2	10.8	2.26	250	180	100	95	30	PCO+	
21	28	M	0	160	74	28.9	120/80	96	90	76	1.18	15.2	0.17	12.6	5.2	2.42	4.5	13.2	1.2	11.6	0.4	292	200	96	140	28	PCO+	
22	26	M	0	166	65	23.6	120/80	86	84	101	0.83	9	0.11	14.2	5.2	2.73	3.4	10.3	1.1	12	2.4	260	210	90	110	30	PCO+	
23	26	M	0	152	70	30.3	110/70	98	88	100	0.88	10.2	0.12	12.4	4.2	2.95	8.8	10.3	1	25	2.8	280	263	168	195	34	PCO+	
24	24	M	0	160	65	25.4	120/80	87	88	110	0.80	22	0.25	10.2	4.2	2.43	4.2	9.6	1.2	12.3	2.3	272	180	120	140	32	PCO+	
25	28	M	0	166	68	24.7	90/70	87	80	98	0.82	6.8	0.09	10.3	5.6	1.84	4.2	11.6	1.2	19.4	1.5	294	180	120	140	32	PCO+	
26	22	UM	0	160	65	25.4	120/80	87	67	91	0.74	9.8	0.15	10.9	5.6	1.95	3.2	11.6	0.9	18.6	2.6	365	176	94	140	32	PCO+	
27	20	UM	0	160	65	25.4	100/70	87	67	91	0.74	7.2	0.11	14.2	5.2	2.73	4.1	0.2	1.4	7.9	3.6	365	176	94	140	32	PCO+	
28	24	UM	0	158	65	26	90/70	90	67	94	0.71	15.2	0.23	10.9	5.6	1.95	2.8	8.6	1.1	15.2	2.8	280	197	93	124	30	PCO+	
29	22	UM	0	164	66	24.5	110/70	87	88	110	0.80	6.2	0.07	10.2	4.2	2.43	3.14	12.3	0.9	15.4	2.26	294	190	100	120	40	PCO+	
30	20	UM	0	158	64	25.6	130/80	90	79	68	1.16	9.2	0.12	12.6	4.2	3.00	2.3	7.6	1.18	8.9	3.6	525	197	93.4	124	30	PCO+	
1	29	M	4	164	69	25.7	110/92	90	80	90	0.89	14	0.18	12.2	5	2.44	2.6	12	1.08	10.86	2.2	286	180	104	140	30	PCO+	
2	27	M	4	166	67	24.3	150/100	86	84	110	0.76	8	0.10	12	6	2.00	3.14	12.6	0.9	6.5	4.46	300	188	100	120	41	PCO+	
3	25	M	4	162	78	29.7	110/70	98	89	126	0.71	3.9	0.04	14	5	2.80	2.4	14	1.1	7.6	3.4	270	200	90	98	32	PCO+	

Patient ID	Age	MS	Wks	HT	WT	BMI	BP	AC	FBS	PPBS	FBS/PPBS	F.I	I/G	LH	FSH	LH/FSH	TSH	PRO	T.Testo	F.Testo	Serum Andro	DHEAS	TC	TGL	LDL	HDL	USG	PI
4	29	M	4	156	64	26.3	140/100	90	92	106	0.87	15	0.16	12	4	3.00	4	10.6	0.1	8	2.6	300	208	92	100	32	PCO+	
5	26	M	4	164	48	17.8	120/80	74	90	86	1.05	8.3	0.09	12	6	2.00	4	10.1	0.8	11	0.4	280	198	96		32	PCO+	
6	24	M	4	160	58	22.7	120/70	84	96	84	1.14	6.2	0.06	12	6.2	1.94	3.2	9.6	0.9	9.3	2.26	250	188	100	94	30	PCO+	
7	24	M	4	164	63	23.4	120/80	84	88	124	0.71	4.2	0.05	10.3	4.3	2.40	2.44	10.3	1.12	7.2	3.8	270	208	98.4	94	30	PCO+	
8	26	M	4	156	50	20.5	140/92	80	88	110	0.80	9.2	0.10	10.4	5	2.08	2.76	12	0.8	8.6	2.24	206	212	98	94	32	PCO+	
9	23	M	4	164	60	22.3	100/70	82	64	79	0.81	16	0.25	10.4	5.2	2.00	2.2	10.2	1.1	10.6	2.1	280	200	90	98	32	PCO+	
10	24	M	4	166	52	18.9	100/70	76	78	110	0.71	9.2	0.12	10	4	2.50	1.2	13.4	0.7	7.2	3.1	268	208	100	90	32	PCO+	
11	19	UM	4	152	65	28.1	100/70	94	90	114	0.79	16	0.18	12	6	2.00	4.2	10	1.1	10.6	2.1	280	208	96	100	32	PCO+	
12	22	UM	4	152	40	17.3	100/70	92	74	110	0.67	7.6	0.10	10	5	2.00	2.8	9.2	0.9	7.5	3	260	208	88	108	30	PCO+	
13	22	UM	4	162	76	29	100/70	98	92	110	0.84	8	0.09	10	5.2	1.92	5	5.2	0.9	6.2	4.2	428	198	90	98	32	PCO+	
14	20	UM	4	150	57	25.3	100/70	87	86	110	0.78	10.1	0.12	14	5.6	2.50	3.1	13.2	0.7	8.2	2.1	260	168	100	136	30	PCO+	
15	20	UM	4	160	60	23.4	100/70	84	79	67	1.18	7.6	0.10	15.3	7.2	2.13	3.2	10.6	1.04	9.1	2.3	350	198	98	90	32	PCO+	
16	24	UM	4	154	63	26.6	90/70	92	98	84	1.17	17	0.17	12	4	3.00	4	10.3	0.9	8.7	2.26	300	196	90	96	30	PCO+	
17	30	M	4	164	60	22.3	90/70	82	90	86	1.05	6.5	0.07	12	6	2.00	4	9.6	1.2	10.3	2.4	262	188	88	98	30	PCO+	
18	28	M	4	158	60	24	150/100	86	96	82	1.17	10.3	0.11	14	4	3.50	3.8	9.2	8.6	0.8	2.8	240	188	98	88	30	PCO+	
19	24	M	4	160	62	24.2	100/70	86	90	88	1.02	6.5	0.07	12	6	2.00	3.2	10.3	0.9	10.4	2.8	240	178	90	98	30	PCO+	
20	20	UM	4	160	58	22.7	120/80	84	96	82	1.17	7.5	0.08	14	6	2.33	3.4	10.4	1.2	10.8	2.26	248	182	98	93	30	PCO+	
21	28	M	4	160	74	28.9	130/80	96	90	86	1.05	15	0.17	12	5	2.40	4	13.2	1.2	11.6	0.4	290	198	94	138	30	PCO+	
22	26	M	4	166	65	23.6	120/80	86	80	90	0.89	9	0.11	14	5	2.80	3.4	10.3	1.1	12	2.4	260	208	88	108	30	PCO+	
23	26	M	4	152	70	30.3	110/70	98	88	110	0.80	10.2	0.12	12.6	4	3.15	3.8	10.3	1	25	2.8	276	260	150	90	34	PCO+	
24	24	M	4	160	65	25.4	220/70	87	88	110	0.80	22	0.25	10	4.6	2.17	4.2	9.6	1.2	12	2.3	270	178	118	138	32	PCO+	
25	28	M	4	166	68	24.7	90/70	87	80	98	0.82	6.8	0.09	10	5	2.00	4.2	11.6	1.2	19	1.5	290	178	118	138	32	PCO+	
26	22	UM	4	160	65	25.4	124/82	87	62	94	0.66	9.8	0.16	10.9	5.6	1.95	3.2	11.6	0.9	18	2.6	360	174	90	138	32	PCO+	
27	20	UM	4	160	65	25.4	110/70	87	70	90	0.78	7.2	0.10	14	5	2.80	4.1	10	1.4	7.9	3.6	360	174	92	138	32	PCO+	
28	24	UM	4	158	95	26	90/70	90	67	91	0.74	15	0.22	10	5	2.00	2.8	8.4	1.1	15	2.8	280	196	92	124	30	PCO+	
29	22	UM	4	164	66	24.5	110/70	87	88	110	0.80	6.2	0.07	10	4	2.50	3.14	12	0.9	15	2.26	290	188	98	118	41	PCO+	
30	20	UM	4	158	64	25.6	130/80	90	80	97	0.82	9.2	0.12	12	4	3.00	2.3	7.6	1.18	8.9	3.6	520	196	90.2	122	30	PCO+	
1	29	M	8	164	68	25.3	110/70	87	80	94	0.85	14	0.18	14	5	2.80	2.4	12.6	1.08	10.8	2.2	280	180	104	140	30	PCO+	
2	27	M	8	166	67	24.3	150/90	86	84	106	0.79	8	0.10	12.3	6.2	1.98	3.1	10.4	0.8	6.5	4.4	300	188	100.2	120	41	PCO+	
3	25	M	8	162	78	29.7	100/70	98	88	124	0.71	3.9	0.04	12.2	6	2.03	2.3	13.8	1	7.5	3.4	270	210	90	98	32	PCO+	
4	29	M	8	156	62	25.5	140/94	90	90	106	0.85	14.8	0.16	11.2	5.2	2.15	4	10.4	0.1	8	2.6	300	208	92	110	32	PCO+	
5	26	M	8	164	48	17.8	120/80	74	90	76	1.18	8.3	0.09	10.2	5.8	1.76	3.8	10	0.8	11	0.4	280	198	96		32	PCO+	
6	24	M	8	160	56	21.9	120/80	82	96	82	1.17	6.2	0.06	10.2	5.6	1.82	3.2	9.6	0.9	9	2.2	250	188	100	94	32	PCO+	
7	24	M	8	164	62	23.1	120/70	84	89	124	0.72	4.2	0.05	9.2	4	2.30	2.4	9.8	1.12	7.2	3.8	270	208	98.4	92	30	PCO+	

Patient ID	Age	MS	Wks	HT	WT	BMI	BP	AC	FBS	PPBS	FBS/PPBS	F.I	I/G	LH	FSH	LH/FSH	TSH	PRO	T.Testo	F.Testo	Serum Andro	DHEAS	TC	TGL	LDL	HDL	USG	PI
8	26	M	8	156	50	20.5	144/92	80	80	78	1.03	16	0.20	10	5.1	1.96	2.6	12.2	0.8	8.6	2.24	206	212	98	92	34	PCO+	
9	23	M	8	164	61	22.7	100/70	84	64	80	0.80	3.5	0.05	10	5	2.00	2.18	10	0.7	12	1.8	212	210	90	98	32	PCO+	
10	24	M	8	166	52	18.9	140/90	76	78	110	0.71	9.2	0.12	10	4.4	2.27	1.1	13.2	0.7	7.2	3.1	268	208	98	90	32	PCO+	
11	19	UM	8	152	65	28.1	120/70	94	90	114	0.79	16	0.18	10.2	5.6	1.82	4	9.8	1.1	10	2.1	280	208	96	98	32	PCO+	
12	22	UM	8	152	40	17.3	90/70	72	76	96	0.79	7.6	0.10	9.2	6.2	1.48	2.7	9.2	0.9	7.5	3	260	208	86	108	30	PCO+	
13	22	UM	8	162	75	28.6	110/70	98	94	114	0.82	8	0.09	9.6	5	1.92	5	5.2	0.9	6.2	4.2	420	196	90	98	30	PCO+	
14	20	UM	8	150	57	25.3	90/70	87	86	110	0.78	10.1	0.12	12.4	6	2.07	3	13	0.7	8.2	2.1	260	168	98	136	32	PCO+	
15	20	UM	8	160	60	23.4	100/70	84	84	102	0.82	7.4	0.09	14.8	7.6	1.95	3.1	10.6	1.04	9.1	2.6	350	198	96	90	34	PCO+	
16	24	UM	8	154	60	25.3	100/70	87	102	84	1.21	17	0.17	11.2	4.2	2.67	4	10.3	0.9	8.7	2.26	300	196	90	96	32	PCO+	
17	30	M	8	164	58	21.6	100/70	82	90	100	0.90	6.5	0.07	11.6	5.2	2.23	4	9.6	1.2	10	2.4	262	186	90	98	30	PCO+	
18	28	M	8	158	60	24	140/90	86	96	100	0.96	10.3	0.11	12.6	4.2	3.00	3.8	9.2	0.8	8	2.6	232	190	98	90	30	PCO+	
19	24	M	8	160	60	23.4	90/70	84	90	76	1.18	6.5	0.07	10.2	5.6	1.82	3.1	10.2	0.8	8.2	2.6	230	180	90	98	32	PCO+	
20	20	UM	8	160	58	22.7	120/80	84	96	100	0.96	7.5	0.08	11.6	5.2	2.23	3	10.4	1.2	10.8	2.2	248	182	100	95	32	PCO+	
21	28	M	8	160	72	28.1	132/82	94	90	70	1.29	15	0.17	11.6	5.2	2.23	4	13.2	1.2	11.4	0.4	290	198	94	138	30	PCO+	
22	26	M	8	166	64	23.2	120/80	84	84	100	0.84	9.2	0.11	12.2	6	2.03	3.3	10.2	1.1	12	2.4	260	208	90	108	30	PCO+	
23	26	M	8	152	68	29.4	110/70	96	88	100	0.88	10	0.11	11.8	4.2	2.81	3.6	10.4	1	25	2.8	276	260	150	190	36	PCO+	
24	24	M	8	160	65	25.4	120/80	87	86	107	0.80	20	0.23	10.3	5.2	1.98	4	9.6	1.2	12	2.3	270	178	118	136	32	PCO+	
25	28	M	8	166	68	24.7	100/70	87	88	106	0.83	6.8	0.08	9.6	5.8	1.66	4	11	1.2	18	1.5	290	178	118	138	32	PCO+	
26	22	UM	8	160	64	25	120/70	87	70	94	0.74	9.8	0.14	10	5.2	1.92	3.2	11.6	0.9	18	2.6	356	174	90	138	32	PCO+	
27	20	UM	8	160	64	25	110/70	87	70	90	0.78	7.2	0.10	13.3	6.2	2.15	10.2	4.1	1.4	7.9	3.5	360	174	92	138	34	PCO+	
28	24	UM	8	158	64	25.6	100/70	90	70	91	0.77	15	0.21	10.6	5.2	2.04	2.6	8.4	1.1	15	2.8	280	196	92	120	32	PCO+	
29	22	UM	8	164	65	24.2	100/70	86	86	108	0.80	6.2	0.07	8.6	4	2.15	3.1	12.4	0.9	15	2.26	290	188	96	118	41	PCO+	
30	20	UM	8	158	63	25.2	120/80	87	80	97	0.82	9.2	0.12	11.6	5	2.32	2.2	7.5	1.18	8.9	3.6	520	196	90	122	32	PCO+	
1	29	M	12	164	68	25.3	100/70	87	82	104	0.79	12	0.15	12.6	6.2	2.03	2	12	0.07	9.6	2	276	178	100	138	32	PCO+	
2	27	M	12	166	66	24	140/90	86	84	110	0.76	7.8	0.09	10.4	4.3	2.42	3.1	10.4	0.8	5.8	4.4	290	186	100.2	121	42	PCO+	
3	25	M	12	162	76	29	110/70	96	89	124	0.72	3.9	0.04	10.4	5.2	2.00	2.3	13.6	1	6.2	3.2	269	210	92	98	34	PCO+	
4	29	M	12	156	62	25.5	140/90	90	94	110	0.85	13.2	0.14	10.6	5	2.12	4.2	10.4	0.1	6.9	2.5	282	210	90	100	34	PCO+	
5	26	M	12	164	49	18.2	120/70	74	90	76	1.18	8.4	0.09	10.4	5.6	1.86	3.8	10	0.8	9.6	0.4	278	200	94		34	PCO+	
6	24	M	12	156	56	21.9	120/70	82	96	100	0.96	6.1	0.06	9.2	5.4	1.70	3.2	9.2	0.8	8.2	2.2	248	190	102	92	32	PCO+	
7	24	M	12	162	62	23.1	120/70	84	89	120	0.74	4.2	0.05	9	4.2	2.14	2.4	9.8	1.1	7	3.5	268	210	102	92	30	PCO+	
8	26	M	12	156	52	21.4	140/90	80	80	78	1.03	14.2	0.18	9.2	4.8	1.92	2.6	12	0.7	7	2.2	204	214	100	94	34	PCO+	
9	23	M	12	164	60	22.3	100/70	82	64	82	0.78	3.5	0.05	8.6	4.2	2.05	2.2	10.2	0.7	10	1.7	210	220	92	98	34	PCO+	
10	24	M	12	166	50	18.1	138/90	74	76	8	9.50	9.2	0.12		4.9	0.00	1.2	13.2	0.6	7	2.8	263	210	102	92	34	PCO+	
11	19	UM	12	152	63	27.3	110/70	92	96	110	0.87	14	0.15	9.4	5.2	1.81	4	9.8	1	8	2	272	210	98	100	34	PCO+	

Patient ID	Age	MS	Wks	HT	WT	BMI	BP	AC	FBS	PPBS	FBS/PPBS	F.I	I/G	LH	FSH	LH/FSH	TSH	PRO	T.Testo	F.Testo	Serum Andro	DHEAS	TC	TGL	LDL	HDL	USG	PI
12	22	UM	12	152	40	17.3	90/70	72	82	96	0.85	7.6	0.09	8.4	6	1.40	2.7	9.2	0.8	7.1	3	255	210	90	110	32	PCO+	
13	22	UM	12	162	70	26.7	110/70	92	96	12	8.00	8.2	0.09	9	4.8	1.88	4.8	5.2	0.9	5.8	3.8	396	200	92	100	32	PCO+	
14	20	UM	12	150	57	24.9	90/70	87	86	110	0.78	10	0.12	12	6.4	1.88	3	12.2	0.7	8	2.1	242	170	102	138	32	PCO+	
15	20	UM	12	160	60	23.4	100/70	84	84	100	0.84	7.4	0.09	14	7	2.00	3	10.6	1	7.2	2.3	300	200	100	94	34	PCO+	
16	24	UM	12	154	58	24.5	100/70	87	110	90	1.22	12.3	0.11	10.3	5.2	1.98	3.8	10.3	0.8	6.4	2.2	280	198	92	98	32	PCO+	
17	30	M	12	164	58	21.6	100/80	82	90	76	1.18	6.5	0.07	10.3	5.4	1.91	3.8	9.5	1	8.6	2	240	190	88	100	32	PCO+	
18	28	M	12	158	58	23.2	140/90	84	96	82	1.17	10.3	0.11	12	4	3.00	3.6	9.1	0.7	8	2.6	232	188	100	88	32	PCO+	
19	24	M	12	160	60	23.4	90/70	84	90	76	1.18	6.5	0.07	10	5.2	1.92	3.1	10.2	0.8	8	2.6	230	178	92	100	32	PCO+	
20	20	UM	12	160	58	22.7	110/70	84	96	82	1.17	7.5	0.08	10.6	5.3	2.00	3	10.6	1.1	8.6	2.2	242	180	98	95	32	PCO+	
21	28	M	12	160	72	28.1	120/82	94	90	76	1.18	14.2	0.16	11	4.8	2.29	3.8	13	1.2	10.3	0.4	282	200	96	140	30	PCO+	
22	26	M	12	166	65	23.6	120/70	86	84	101	0.83	8.8	0.10	12	6	2.00	3.3	10.2	1.1	11	2	255	210	88	110	32	PCO+	
23	26	M	12	152	68	29.4	110/70	96	96	110	0.87	9.8	0.10	11.6	4	2.90	3.6	10.3	1	20	2.6	270	263	158	190	36	PCO+	
24	24	M	12	160	64	25	110/70	87	86	108	0.80	20	0.23	9.6	4.9	1.96	4	9.5	1.1	11.6	2.2	268	176	118	140	32	PCO+	
25	28	M	12	166	66	24	100/70	86	88	106	0.83	6.6	0.08	9.6	5	1.92	4	11.6	1.2	15.2	1.4	280	178	118	140	34	PCO+	
26	22	UM	12	160	64	25	120/80	87	70	100	0.70	9.8	0.14	9.8	5.2	1.88	3.2	11.6	0.9	15.2	2.5	324	176	94	140	34	PCO+	
27	20	UM	12	160	64	25	100/70	87	80	100	0.80	7.2	0.09	13	6	2.17	4	10.4	1.3	7.7	3.2	358	176	94	140	34	PCO+	
28	24	UM	12	158	64	25.6	100/70	90	78	94	0.83	14.6	0.19	10	4.2	2.38	2.6	8.6	1.1	13.2	2.7	270	197	93	120	32	PCO+	
29	22	UM	12	164	65	24.2	110/70	86	86	110	0.78	6.2	0.07	8.8	4.2	2.10	3.1	12.3	0.8	12.3	2.24	283	190	98	120	42	PCO+	
30	20	UM	12	158	63	25.2	120/80	87	84	102	0.82	9.2	0.11	11.8	5.2	2.27	2.2	7.5	1.18	8.6	3.5	500	197	90	124	32	PCO+	
1	29	M	16	164	65	24.2	110/70	86	84	100	0.84	12	0.14	12.4	6	2.07	2	12.4	0.07	9.6	2	270	178	100	138	32	PCO+	
2	27	M	16	166	66	24	140/90	86	84	106	0.79	7.8	0.09	10.4	4.4	2.36	3.1	6.2	0.9	5.6	4.4	280	186	100.2	120	42	PCO+	
3	25	M	16	162	74	28.2	100/70	94	88	126	0.70	3.9	0.04	8.4	6.4	1.31	2	13.6	1	6	3.2	268	200	92	98	34	PCO+	
4	29	M	16	156	60	24.7	140/90	87	94	110	0.85	13	0.14	2.8	10.4	0.27	4.2	10	0.1	6.9	2.5	282	208	92	110	34	PCO+	
5	26	M	16	164	50	18.6	120/70	76	100	80	1.25	8.4	0.08	9.6	5	1.92	3.7	10.2	0.8	9.6	0.4	278	198	96		34	PCO+	
6	24	M	16	160	52	22.7	120/70	84	96	100	0.96	6.1	0.06	8.3	5.2	1.60	3.4	9.2	0.8	8.2	2.2	248	188	100	94	34	PCO+	
7	24	M	16	164	62	23.1	120/70	84	89	124	0.72	4.2	0.05	8.8	4	2.20	2.3	9.8	1.1	7	3.5	268	208	102	94	32	PCO+	
8	26	M	16	156	52	21.4	130/90	80	88	110	0.80	14	0.16	9.2	4.8	1.92	2.5	12	0.7	7	2.2	204	212	98	92	34	PCO+	
9	23	M	16	164	59	21.9	100/70	82	64	8	8.00	3.5	0.05	7.6	6.2	1.23	2.2	10.4	0.7	7	1.7	200	210	92	98	34	GES.SAC	
10	24	M	16	166	150	18.1	130/90	74	76	110	0.69	9.2	0.12	6.4	5.8	1.10	1.1	13	0.6	6.6	3.1	260	210	102	92	34	GES.SAC	
11	19	UM	16	152	60	26	110/70	90	88	112	0.79	12	0.14	8	5.2	1.54	3.8	10	1	8	2	272	208	96	100	34	PCO+	
12	22	UM	16	152	42	18.2	100/70	74	76	100	0.76	7.6	0.10	8.1	4.6	1.76	2.6	9.2	0.8	7.1	3	255	208	90	110	32	PCO+	
13	22	UM	16	162	70	26.7	100/70	92	94	114	0.82	8.2	0.09	8.1	7.6	1.07	4.7	5	0.9	5.6	3.8	396	198	90	98	32	PCO+	
14	20	UM	16	150	54	24	90/70	86	62	112	0.55	10	0.16	12	6.2	1.94	3.1	13.2	0.7	8	2.1	240	168	100	138	32	PCO+	
15	20	UM	16	160	58	22.7	90/70	84	84	102	0.82	7.4	0.09	12.6	6.2	2.03	3	10.6	1	7.2	2.2	300	198	98	90	34	PCO+	

Patient ID	Age	MS	Wks	HT	WT	BMI	BP	AC	FBS	PPBS	FBS/PPBS	F.I	I/G	LH	FSH	LH/FSH	TSH	PRO	T.Testo	F.Testo	Serum Andro	DHEAS	TC	TGL	LDL	HDL	USG	PI	
16	24	UM	16	154	58	24.5	100/70	87	112	90	1.24	12	0.11	10	5.4	1.85	3.8	10.3	0.8	6.4	2.2	280	196	90	96	32	PCO+		
17	30	M	16	164	60	22.3	100/70	82	90	76	1.18	6.5	0.07	9.6	7.5	1.28	3.8	9.5	1	8	2.4	240	188	90	98	32	PCO+		
18	28	M	16	158	58	23.2	140/90	84	96	84	1.14	10.3	0.11	10.3	6.2	1.66	3.6	9.1	0.7	7.2	2.5	210	190	98	90	32	GES.SAC		
19	24	M	16	160	60	23.4	90/70	84	90	82	1.10	6.5	0.07	8.3	4.2	1.98	3.2	10.2	0.8	8	2.6	230	178	92	100	32	PCO+		
20	20	UM	16	160	57	22.3	110/70	82	76	84	0.90	7.5	0.10	8.8	6	1.47	2.8	10.4	1	8.4	2.2	242	180	98	95	32	PCO+		
21	28	M	16	160	70	27.3	120/80	92	90	96	0.94	14.2	0.16	10.3	4.6	2.24	3.8	13	1.2	10.3	0.4	280	198	96	140	30	PCO+		
22	26	M	16	166	67	24.3	110/70	86	84	110	0.76	8.8	0.10	10.4	5.2	2.00	3.4	10.2	1.1	11	2	255	208	90	108	32	PCO+		
23	26	M	16	152	66	28.6	100/80	96	96	110	0.87	9.8	0.10	11.8	4.2	2.81	3.6	10.3	1	20	2.6	270	283	58	195	36	PCO+		
24	24	M	16	160	64	25	110/70	87	88	110	0.80	20	0.23	9.8	4.2	2.33	4.1	9.5	1.1	11.6	2.2	268	180	120	140	35	PCO+		
25	28	M	16	166	68	24.7	108/70	87	80	98	0.82	6.6	0.08	9.8	5.2	1.88	3.8	11	1.2	15.2	1.4	280	180	120	140	34	PCO+		
26	22	UM	16	160	63	24.6	110/80	87	82	110	0.75	9.8	0.12	9.7	5	1.94	3.1	11.6	0.9	15.2	2.5	320	174	90	138	34	PCO+		
27	20	UM	16	160	63	24.6	100/70	87	80	102	0.78	7.2	0.09	11.6	5.2	2.23	4	10.2	1.3	7.7	3.2	358	174	92	140	34	PCO+		
28	24	UM	16	158	62	24.8	110/70	87	78	94	0.83	13	0.17	9.6	4	2.40	2.6	8.6	1.1	13	2.7	270	197	92	124	32	PCO+		
29	22	UM	16	164	64	23.8	100/70	86	88	108	0.81	6.2	0.07	8.6	5.2	1.65	3.1	12.3	0.9	12.3	2.24	283	188	96	118	42	PCO+		
30	20	UM	16	158	62	24.8	120/84	87	84	100	0.84	9.2	0.11	10.6	4.6	2.30	2.2	7.6	1.18	8.6	3.5	500	196	93	124	32	PCO+		
1	29	M	20	164	64	23.8	110/80	86	84	101	0.83	10	0.12	12.4	6.1	2.03	2	12	1	7	1.9	220	178	100	138	32	GES.SAC		
2	27	M	20	166	63	22.9	140/90	84	84	110	0.76	7.8	0.09	10.4	4.3	2.42	3.1	6.2	0.9	4.2	3	275	180	100	120	42	GES.SAC		
3	25	M	20	162	72	27.4	110/70	92	90	120	0.75	3.9	0.04	8.4	6	1.40	2	13.6	1	4.8	2.9	264	200	90	98	34	PCO+		
4	29	M	20	156	60	24.7	140/90	87	90	106	0.85	10.2	0.11	8.4	9.2	0.91	3.9	10	0.1	7	2.2	270	210	90	110	34	GES.SAC		
5	26	M	20	164	50	18.6	120/70	76	110	80	1.38	8.4	0.08	9.6	4.2	2.29	3.7	10.2	0.8	9.6	0.3	278	198	94		34	PCO+		
6	24	M	20	160	58	22.7	120/80	84	96	82	1.17	6.2	0.06	8.4	5	1.68	3.2	9.6	0.8	8.2	2.2	248	188	100	92	34	PCO+		
7	24	M	20	164	62	23.1	120/70	84	88	126	0.70	4.2	0.05	8.8	4.1	2.15	2.3	9.8	1.1	7	3.4	268	208	100	92	32	PCO+		
8	26	M	20	156	52	21.4	130/90	80	80	78	1.03	14	0.18	8	5.9	1.36	2.5	12.2	0.7	7	2.2	204	212	98	92	34	PCO+		
9	23	M	20																										
10	24	M	20																										
11	19	UM	20	152	59	25.5	110/70	90	88	110	0.80	9	0.10	7.6	5.6	1.36	3.8	10	1	6.2	2	263	210	98	102	34		CYC.REG	
12	22	UM	20	152	40	17.3	100/70	72	76	110	0.69	7.6	0.10	7.2	8.6	0.84	2.6	9.2	0.8	7	2.8	243	210	90	110	32		CYC.REG	
13	22	UM	20	162	68	25.9	100/70	90	94	112	0.84	8.2	0.09	7.8	5.2	1.50	4.7	5	0.9	5.6	3.8	396	198	90	98	32	PCO+		
14	20	UM	20	150	54	24	90/70	86	86	110	0.78	10	0.12	10.3	5.2	1.98	3.1	13.6	0.7	8	2.1	240	168	102	140	32	PCO+		
15	20	UM	20	160	58	22.7	90/70	84	79	102	0.77	7.6	0.10	10.3	6	1.72	2.8	10.6	1	7	2.2	300	198	98	90	34	PCO+		
16	24	UM	20	154	55	23.2	100/70	84	112	80	1.40	9.6	0.09	8.2	6.4	1.28	3.8	10.3	0.8	5.2	2	275	198	92	98	32		CYC.REG	
17	30	M	20	164	60	22.3	100/70	82	90	76	1.18	6.5	0.07	8.4	5.2	1.62	3.8	9.5	0.9	7	2.3	220	190	90	100	37	GES.SAC		
18	28	M	20																										
19	24	M	20	160	60	23.4	90/70	84	90	110	0.82	6.5	0.07	7.5	5.8	1.29	3.2	10.2	0.8	6.5	2.6	115	180	92	100	32	GES.SAC		

Patient ID	Age	MS	Wks	HT	WT	BMI	BP	AC	FBS	PPBS	FBS/PPBS	F.I	I/G	LH	FSH	LH/FSH	TSH	PRO	T.Testo	F.Testo	Serum Andro	DHEAS	TC	TGL	LDL	HDL	USG	PI	
20	20	UM	20	160	57	22.3	100/70	82	96	84	1.14	7.5	0.08	8.6	7.2	1.19	2.8	10.6	1	7.2	2.03	230	180	100	94	32		CYC.REG	
21	28	M	20	160	69	27	120/80	92	90	82	1.10	14	0.16	10.2	4.2	2.43	3.8	13	1.2	10.2	0.4	280	200	96	140	30	PCO+		
22	26	M	20	166	67	24.3	110/70	86	84	100	0.84	8.8	0.10	10.2	5.4	1.89	3.4	10.2	1.1	10.8	2	255	208	90	108	32	PCO+		
23	26	M	20	152	66	28.6	110/70	96	96	108	0.89	9.8	0.10	11	5.2	2.12	3.4	10.2	1	18	2.6	270	260	158	195	36	PCO+		
24	24	M	20	160	64	25	110/70	87	88	110	0.80	20	0.23	9.8	4.2	2.33	4.1	9.6	1.1	11	2.2	268	180	120	140	35	PCO+		
25	28	M	20	166	66	24	108/90	86	84	108	0.78	6.6	0.08	9.8	5.6	1.75	3.8	11	1.2	5	1.4	280	178	120	140	34	PCO+		
26	22	UM	20	160	63	24.6	110/80	87	82	110	0.75	9.8	0.12	9	6.2	1.45	3	11.6	0.9	15	2.5	320	174	90	138	34	PCO+		
27	20	UM	20	160	63	24.6	110/70	87	80	110	0.73	7.2	0.09	10.4	5.2	2.00	4	10.2	1.2	7.7	3.2	358	174	92	138	34	PCO+		
28	24	UM	20	158	62	24.8	110/70	87	78	90	0.87	13	0.17	9.4	5.1	1.84	2.6	8.6	1.1	13	2.7	270	196	92	124	34	PCO+		
29	22	UM	20	164	63	23.4	110/70	86	84	110	0.76	6.2	0.07	7.8	5	1.56	3	12.3	0.9	12	2.24	283	188	98	118	42	PCO+		
30	20	UM	20	158	62	24.8	124/84	87	84	102	0.82	9.2	0.11	10.8	4.2	2.57	2.1	7.6	1.18	8.5	3.5	500	196	94	124	30	PCO+		
1	29	M	24																										
2	27	M	24																										
3	25	M	24																										
4	29	M	24																										
5	26	M	24	164	49	18.2	120/70	74	90	86	1.05	8.3	0.09	8	6.2	1.29	3.7	10.2	0.7	6.9	0.3	272	200	94		34	PCO+		
6	24	M	24	160	58	22.7	120/80	84	96	84	1.14	6.2	0.06	6.9	5.6	1.23	3.2	9.6	0.8	6.2	2	243	190	102	94	34	GES.SAC		
7	24	M	24	164	62	23.1	110/70	84	88	126	0.70	4.2	0.05	7	4.3	1.63	2.3	9.8	1.1	6.4	3	260	110	102	92	32	GES.SAC		
8	26	M	24	156	52	21.4	130/90	80	80	98	0.82	10.1	0.13	7.2	5.9	1.22	2.7	12.2	0.7	6.2	2.18	200	214	100	94	34	GES.SAC		
9	23	M	24																										
10	24	M	24																										
11	19	UM	24																										
12	22	UM	24																										
13	22	UM	24	162	68	25.9	100/70	90	94	112	0.84	8.2	0.09	7.8	5	1.56	4.7	5	0.9	5	3.3	352	200	92	100	32		CYC.REG	
14	20	UM	24	150	52	23.1	90/70	84	86	110	0.78	10.1	0.12	8.6	5	1.72	3.1	13.2	0.7	7.1	2.1	220	270	102	138	32		CYC.REG	
15	20	UM	24	160	58	22.7	100/70	84	99	102	0.97	7.6	0.08	7.2	8.6	0.84	2.8	10.6	1	6.5	2.2	270	200	100	94	34		CYC.REG	
16	24	UM	24																										
17	30	M	24																										
18	28	M	24																										
19	24	M	24																										
20	20	UM	24																										
21	28	M	24	160	69	27	120/90	92	90	82	1.10	12.1	0.13	10.4	5.2	2.00	3.8	13	1	9.2	0.4	278	200	96	140	30	PCO+		
22	26	M	24	166	68	24.7	120/80	87	84	100	0.84	8.8	0.10	10.2	5.4	1.89	3.4	10.2	1.1	10.6	2	250	208	90	110	32	PCO+		
23	26	M	24	152	65	28.1	100/70	94	96	110	0.87	9	0.09	11	5.2	2.12	3	10.2	0.8	15	2.6	270	263	158	190	36	PCO+		

Patient ID	Age	MS	Wks	HT	WT	BMI	BP	AC	FBS	PPBS	FBS/PPBS	F.I	I/G	LH	FSH	LH/FSH	TSH	PRO	T.Testo	F.Testo	Serum Andro	DHEAS	TC	TGL	LDL	HDL	USG	PI
24	24	M	24	160	64	25	110/70	87	88	110	0.80	18	0.20	9.8	4.2	2.33	4	9.6	1	10.3	2	265	180	120	140	35	PCO+	
25	28	M	24	166	70	25.4	110/70	87	84	100	0.84	6.8	0.08	9.6	5.8	1.66	3.8	11	1.1	10	1.4	278	180	120	140	34	PCO+	
26	22	UM	24	160	63	24.6	110/80	87	82	110	0.75	9.8	0.12	9.2	6	1.53	3	11.5	0.8	11.6	2.4	300	176	94	140	34	PCO+	
27	20	UM	24	160	63	24.6	100/70	87	80	110	0.73	7.2	0.09	10.4	5.2	2.00	4	10.2	1.1	7	3.1	350	176	94	140	34	PCO+	
28	24	UM	24	158	60	24	110/70	86	78	94	0.83	12.2	0.16	9.2	5.2	1.77	2.6	8.6	1	11.4	2.7	262	196	90	120	34	PCO+	
29	22	UM	24	164	63	23.4	110/70	86	84	106	0.79	6.2	0.07	7.8	5	1.56	3	12	0.8	10.4	2.24	278	190	100	120	42	PCO+	
30	20	UM	24	158	60	24	124/84	86	84	102	0.82	9.2	0.11	8.4	5.2	1.62	2.1	7.6	1.18	8.4	3.5	482	197	94	124	32	PCO+	

Patient ID	Age	MS	Wks	HT	WT	BMI	BP	AC	FBS	PPBS	FBS/PPBS	F.I	I/G	LH	FSH	LH/FSH	TSH	PRO	T.Testo	F.Testo	Serum Andro	DHEAS	TC	TGL	LDL	HDL	USG	PI
30	25	M	20	165	50	18.4	120/82	74	96	80	1.20	8.2	0.09	12.2	5.6	2.18	2.8	12	0.6	6.2	2	256	180	88	121	34	PCO+	
1	27	M	24	160	66	25.8	120/70	90	88	110	0.80	14	0.16	12	4.2	2.86	3.1	17.4	1	25	2.25	268	189	100.2	120	28	PCO+	
2	30	M	24	164	67	24.9	120/70	87	100	110	0.91	5.2	0.05	10.2	5.1	2.00	3.1	18	1	20.14	1.5	214	180	120	140	35	PCO+	
3	25	M	24	158	62	24.8	110/70	87				8.6	#DIV/0!	10.2	5	2.04	3.16	10.4	1.18	10.7	2.1	212	190	94	140	35	PCO+	
4	24	M	24	160	61	23.8	110/80	86	79	90	0.88	9.8	0.12	10.2	5.2	1.96	2.3	9.6	1	8.2	2.5	426	196	93	120	52	PCO+	
5	24	M	24	148	54	24.7	114/84	87	90	110	0.82	9.6	0.11	12.4	6	2.07	3	9.6	0.9	9.4	2.4	240	180	90	120	35	PCO+	
6	29	M	24	165	50	18.4	120/80	74	94	84	1.12	10	0.11	12.6	6.4	1.97	3	10.8	0.8	11.8	0.43	263	180	90	118	34	PCO+	
7	26	M	24	168	74	26.2	120/80	90	92	117	0.79	9	0.10	10.4	4.2	2.48	3.6	13	2	19	2.26	288	180	100	140	34	PCO+	
8	28	M	24	170	66	22.8	110/70	84	78	103	0.76	9.2	0.12	12.6	6.6	1.91	3.4	12.2	0.9	8.6	2.8	211	170	100	106	34	PCO+	
9	26	M	24	159	62	24.5	130/80	87	80	120	0.67	11.6	0.15	10.4	5.2	2.00	7.6	15	0.9	20	3.2	276	170	140	140	32	PCO+	
10	28	M	24	154	54	22.8	120/80	84	80	116	0.69	18.8	0.24	12.6	6.2	2.03	2.4	13	0.7	3.8	3	270	226	88	92	38	PCO+	
11	32	M	24	165	52	19.1	120/80	76	76	108	0.70	9.6	0.13	12	6.2	1.94	1.1	13.4	0.7	8.4	3	268	220	90	104	30.2	PCO+	
12	30	M	24	165	78	28.7	120/80	96	78	102	0.76	17	0.22	14	5.2	2.69	8.1	13.2	1	16	1.8	260	220	106	150	32	PCO+	
13	28	UM	24	152	55	23.8	110/80	86	88	112	0.79	9.6	0.11	12.6	6.4	1.97	3.7	10.4	0.5	7.6	2.1	280	230	148	90	34	PCO+	
14	22	UM	24	164	52	19.3	120/70	76	84	92	0.91	7	0.08	12.6	4.2	3.00	3.3	10.6	1.04	4.07	3.8	309	160.2	77	85	30	PCO+	
15	23	UM	24	151	48	21.1	110/80	80	74	110	0.67	7.6	0.10	8.2	3.4	2.41	2.8	7.6	0.9	5.8	3	262	170	148	142	34	PCO+	
16	26	UM	24	162	76	29	120/80	96	92	112	0.82	10.2	0.11	14.4	7.2	2.00	5.2	18	0.9	7.6	4.42	304	234	124	155	44	PCO+	
17	29	UM	24	164	61	22.7	130/80	84	64	82	0.78	3.5	0.05	10	5.6	1.79	2	4.9	0.1	8	1.73	212	180	100	140	35	PCO+	
18	24	UM	24	158	56	22.4	130/80	82	84	96	0.88	15	0.18	9.6	3	3.20	1.8	4.9	0.1	8.7	1.7	162	220	90	98	36	PCO+	
19	22	UM	24	172	65	22	100/70	82	76	84	0.90	5.6	0.07	12.4	6.2	2.00	2.6	14.6	0.1	9.6	2.14	200	170.2	102	106	35	PCO+	
20	20	UM	24	156	47	19.3	100/70	76	76	98	0.78	9.6	0.13	8.8	3.6	2.44	2.7	13.21	0.8	7.6	2.24	207	170	140	142	30.2	PCO+	
21	22	UM	24	154	55	23.2	120/80	84	96	84	1.14	12	0.13	7.4	8.6	0.86	3.2	11	0.9	7.6	2.2	250	190	92	110	30		
22	24	UM	24	158	65	26	120/70	90	96	88	1.09	10.2	0.11	6.4	12	0.53	3	8.6	1	6.8	2.25	266	174	94	138	34		
23	26	M	24	148	48	21.9	100/70	82	90	110	0.82	8.6	0.10				3.2	7.6	0.7	5.4	2.8	239	220	138	150	32		
24	26	M	24	160	62	24.2	100/70	86	78	104	0.75		0.00	6.4	10.4	0.62	2.4	10.6	0.7	7	2.8	260	216	130	160	34		
25	26	UM	24	160	65	25.4	120/80	87	84	100	0.84	18	0.21	10.2	5.4	1.89	3.4	11.6	1.2	15	2.26	264	180	100	120	35	PCO+	
26	23	UM	24	168	74	25.9	110/82	90	90	110	0.82	9	0.10	12.4	6	2.07	2.2	13.2	1.4	19.4	2.26	286	180	100	140	35	PCO+	
27	22	UM	24	170	60	20.8	100/70	80	90	124	0.73	10.2	0.11	12.4	3.2	3.88	3.2	7.6	0.6	10.2	2.26	280	182	94	140	30	PCO+	
28	28	M	24	158	65	26	110/70	90	94	110	0.85	9	0.10	10.4	4	2.60	3	13	1.2	8.9	2.4	254	170	102	140	32	PCO+	
29	24	M	24	154	68	28.7	110/80	96	90	118	0.76	9	0.10	14.2	6	2.37	2.8	12.2	0.7	8.2	2.4	260	180	104	140	30	PCO+	
30	25	M	24	165	50	18.4	120/82	74	90	110	0.82	10	0.11	12	5.2	2.31	2.8	12.2	0.7	6.5	2.4	260	180	90	120	35	PCO+	

GROUP 3 - MYOINOSITOL

Patient ID	Age	MS	Wks	HT	WT	BMI	BP	AC	FBS	PPBS	FBS/PPBS	F.I	I/G	LH	FSH	LH/FSH	TSH	PRO	T.Testo	F.Testo	Serum Andro	DHEAS	TC	TGL	LDL	HDL	USG	PI
1	12	UM	0	160	65	25.4	120/90	87	82	110	0.75	16	0.20	10.4	4.2	2.48	3.14	10	1	19.2	2.3	294	190	100.2	120	32	PCO+	
2	24	UM	0	164	66	24.5	100/70	87	80	98	0.82	3.5	0.04	12.6	5.2	2.42	3.2	18.2	1	19.14	1.53	214	180	120	140	32	PCO+	
3	22	UM	0	158	75	30	110/80	98	79	67	1.18	15.86	0.20	16.4	5.2	3.15	4.1	15.6	1.04	9.1	2.25	365.4	176	94	140	32	PCO+	
4	22	UM	0	160	61.1	23.9	120/70	86	67	91	0.74	9.8	0.15	10.9	5.6	1.95	2.33	7.6	1.18	6.4	3.6	424	197	93.4	124	40	PCO+	
5	26	UM	0	148	59	26.9	90/70	92	90	123	0.73	7.6	0.08	12.6	4.6	2.74	2.5	7.6	0.6	10.8	2.9	343	226	139	160	34	PCO+	
6	22	UM	0	165	49	18	110/80	74	90	72	1.25	10	0.11	12.6	6.4	1.97	3.07	13.29	0.8	11.8	0.4	293	180	90	120	35	PCO+	
7	23	UM	0	168	74	26.2	140/35	90	92	117	0.79	9	0.10	10.07	3.8	2.65	3.6	13.4	4.3	19.14	2.26	288	180	100	140	35	PCO+	
8	22	UM	0	170	66	22.8	110/70	84	78	103	0.76	9.2	0.12	12.6	6.6	1.91	2.3	16.2	0.9	8	3.2	211	171	102	106	35	PCO+	
9	20	UM	0	159	63	24.9	120/70	87	71	121	0.59	11.6	0.16	10.6	4.9	2.16	3.2	18.2	0.9	26.6	3.2	276	170	140	142	35	PCO+	
10	22	UM	0	154	68	28.7	100/70	96	82	116	0.71	12.6	0.15	12.6	4.6	2.74	2.4	10.4	0.7	8.3	3	270	226	88	93	32	PCO+	
11	24	UM	0	165	49.5	18.2	120/80	74	76	108	0.70	9.6	0.13	10.6	3.4	3.12	2.4	13.4	0.7	8.8	3	268	220	90	100	35	PCO+	
12	24	M	0	165	78	28.7	112/82	96	78	102	0.76	17	0.22	14.4	4.6	3.13	4.2	12.5	1.1	20.6	1.8	260	229.7	106	172.3	36	PCO+	
13	26	M	0	152	64	27.7	150/100	94	88	110	0.80	10.4	0.12	10.8	5.6	1.93	3.7	15.4	0.5	8.4	2.1	280	263	168	195	34	PCO+	
14	28	M	0	164	52.5	19.5	130/80	78	84	100	0.84	7	0.08	12.6	4	3.15	3.3	21.8	1.04	4.07	3.8	309	162.1	77.1	85.5	61.2	PCO+	
15	30	M	0	151	40	17.5	140/90	74	74	110	0.67	7.6	0.10	12.6	4.8	2.63	2.86	10.3	0.9	5.6	3	262	170.6	150	143	32.3	PCO+	
16	28	M	0	162	77.5	29.5	130/70	98	92	112	0.82	12.7	0.14	10.6	5.2	2.04	4.1	15.3	0.95	9.2	4.4	646	234.3	124.1	155	42	PCO+	
17	26	M	0	164	61	22.7	150/100	84	60	77	0.78	5.6	0.09	10	4.6	2.17	2.19	14.2	0.6	19.5	1.53	211	180	100	140	35	PCO+	
18	24	M	0	158	58	23.2	170/80	84	83	95	0.87	18.3	0.22	12.6	4.8	2.63	1.8	4.9	0.5	8.8	1.7	162	220	90	100	36	PCO+	
19	24	M	0	172	65	22	130/80	82	78	97	0.80	5.6	0.07	12.4	4.3	2.88	2.64	18.26	0.1	9.6	2.1	200	181	103	106	35.4	PCO+	
20	28	M	0	156	47	19.3	140/100	76	74	94	0.79	8.6	0.12	10.8	5.3	2.04	2.7	13.2	0.16	6.2	2.24	207	170	140	142	30.4	PCO+	
21	24	M	0	154	63	26.6	130/80	92	94	84	1.12	6.6	0.07	12.8	4.6	2.78	4.2	11.3	0.9	9.3	2.26	302	190	92	110	30	PCO+	
22	22	M	0	158	74	29.6	130/80	98	92	78	1.18	12.8	0.14	10.6	4.6	2.30	3.4	17.6	1.04	9	2.2	360	176	96	140	35	PCO+	
23	26	M	0	148	59	26.9	120/70	92	90	120	0.75	8.6	0.10	12.6	5.6	2.25	3.2	7.6	0.6	4.9	2.8	270	226	139	162	39	PCO+	
24	28	M	0	170	64	22.1	140/90	82	78	104	0.75	9.2	0.12	11.6	4.6	2.52	2.4	8.6	1.04	5.69	2.24	214	176	94	140	35	PCO+	
25	30	M	0	160	65	25.4	130/80	87	92	117	0.79	9.6	0.10	12.6	4.2	3.00	3.4	18.25	1.5	25	2.26	294	190	100.2	120	35	PCO+	
26	30	M	0	168	74	26.2	150/100	90	96	110	0.87	9	0.09	12.6	4.8	2.63	2.24	13.4	1.4	19.4	2.26	288	180	100	140	35	PCO+	
27	20	UM	0	170	64	22.1	120/90	82	90	120	0.75	18	0.20	12.6	4.6	2.74	3.56	7.6	0.8	10.4	2.26	280	182	100	140	30	PCO+	
28	22	UM	0	158	74	29.6	124/84	98	94	120	0.78	9	0.10	10.2	5.2	1.96	3.4	13.4	4.9	8.6	2.4	288	170	102	140	30	PCO+	
29	26	M	0	154	68	28.7	120/80	96	82	160	0.51	9	0.11	14.2	5.2	2.73	2.8	13.5	0.7	4.7	2.4	260	180	104	140	28	PCO+	
30	28	M	0	165	50	18.4	120/80	74	94	82	1.15	10	0.12	12.2	5.6	2.18	3.8	13.2	0.87	19.1	0.7	294	180	90	120	35	PCO+	
1	12	UM	4	160	64	25	120/80	87	86	108	0.80	14	0.16	10	4	2.50	3.14	9.2	1	13	2.8	182	182	96	114	34		
2	24	UM	4	164	66	24.5	100/70	87	80	98	0.82	3.5	0.04	10.6	5.2	2.04	3.2	16.2	1	19.1	1.5	214	178	118	135	32		
3	22	UM	4	158	73	29.2	110/80	96	80	97	0.82	15.8	0.20	14.3	5	2.86	4.1	12.3	1.04	9	2.25	360	176	92	134	32		
4	22	UM	4	160	60.03	23.4	120/80	84	67	91	0.74	9.8	0.15	10.8	5.4	2.00	2.33	7.6	1.1	6.4	3.6	400	196	90	120	42		
5	26	UM	4	148	57	26	90/70	90	92	123	0.75	7.6	0.08	12	4.8	2.50	2.5	7.5	0.6	9.8	2.9	336	224	35	158	34		

Patient ID	Age	MS	Wks	HT	WT	BMI	BP	AC	FBS	PPBS	FBS/PPBS	F.I	I/G	LH	FSH	LH/FSH	TSH	PRO	T.Testo	F.Testo	Serum Andro	DHEAS	TC	TGL	LDL	HDL	USG	PI
6	22	UM	4	165	46	16.9	110/80	72	90	82	1.10	10	0.11	12	6	2.00	3.07	12.04	0.8	10.8	0.4	282	180	92	118	35		
7	23	UM	4	168	74	26.2	120/90	90	90	117	0.77	9	0.10	10	3.6	2.78	3.5	12.2	4.3	10.14	2.25	280	178	98	134	35		
8	22	UM	4	170	64	22.1	110/70	82	78	100	0.78	9.2	0.12	12	6	2.00	2.3	14.3	0.9	8	3.2	211	170	100	104	36		
9	20	UM	4	159	63	24.9	120/80	87	80	118	0.68	11.6	0.15	10.9	4.2	2.60	3.2	17.6	0.9	24.6	3.2	290	168	138	140	36		
10	22	UM	4	154	67	28.3	100/70	94	86	110	0.78	12	0.14	12	4	3.00	2.4	9.6	0.7	8.3	3	268	224	86	90	32		
11	24	UM	4	165	49.5	18.2	120/70	74	78	110	0.71	9.6	0.12	10.6	3.8	2.79	2.4	13	0.7	8.6	3	265	218	88	98	35		
12	24	M	4	165	76	27.9	112/80	94	99	100	0.99	15	0.15	14	4	3.50	4.2	11.6	1.1	21.6	1.8	258	229	102	170	36	PCO+	
13	26	M	4	152	64	27.7	150/100	94	86	100	0.86	10	0.12	8.6	4.9	1.76	3.7	14.6	0.5	8	2.1	278	258	162	183	34	PCO+	
14	28	M	4	164	52.5	19.5	130/80	78	86	100	0.86	7	0.08	12.4	4.2	2.95	3.3	17.6	1.04	4	3.8	300	160	77	85	61.4	PCO+	
15	30	M	4	151	40	17.5	140/92	74	76	100	0.76	7.6	0.10	10.4	4.2	2.48	2.86	10	0.9	5.5	3	200	168	148	142	32	PCO+	
16	28	M	4	162	76	29	130/80	96	92	110	0.84	12.7	0.14	9.6	5.6	1.71	4.1	13.2	0.9	9	4.4	640	232	120	154	42	PCO+	
17	26	M	4	164	60	22.3	150/90	82	60	78	0.77	5.6	0.09	10.2	4.4	2.32	2.19	12.2	0.6	17.5	1.5	210	178	98	138	35	PCO+	
18	24	M	4	158	57	22.8	130/80	84	111	90	1.23	18	0.16	10.6	4.2	2.52	1.8	4.8	0.5	8	1.7	160	218	88	98	36	PCO+	
19	24	M	4	172	64	21.6	130/80	82	76	96	0.79	5.6	0.07	12	4	3.00	2.64	17.26	0.1	9	2.1	198	168	100	102	35.4	PCO+	
20	28	M	4	156	47	19.3	140/90	76	72	92	0.78	8.6	0.12	8.4	5.2	1.62	2.7	12.4	0.16	6	2.2	200	168	138	139	32.6	PCO+	
21	24	M	4	154	62	26.1	132/82	90	96	84	1.14	6.6	0.07	12	4.2	2.86	4.2	9.6	0.9	9	2.26	300	186	84	104	32.6	PCO+	
22	22	M	4	158	70	28	134/80	94	90	82	1.10	11.6	0.13	7.3	5	1.46	3.4	15.2	1.04	9	2.2	358	174	94	138	36	PCO+	
23	26	M	4	148	57	26	120/70	90	94	108	0.87	8.6	0.09	9.6	5.2	1.85	3.2	7.4	0.6	4.9	2.8	260	224	134	160	42	PCO+	
24	28	M	4	170	64	22.1	140/90	82	80	110	0.73	9.2	0.12	8.2	4	2.05	2.4	8	1.04	5.6	2.24	214	174	92	138	35	PCO+	
25	30	M	4	160	65	25.4	130/90	87	90	110	0.82	9.6	0.11	12	4.1	2.93	3.4	16.2	1.5	20	2.26	290	188	98	118	36	PCO+	
26	30	M	4	168	74	26.2	150/100	90	92	117	0.79	9	0.10	12.4	4.3	2.88	2.26	10.2	1.4	19	2.26	280	178	98	138	35	PCO+	
27	20	UM	4	170	64	22.1	130/90	82	92	118	0.78	18	0.20	12	4.2	2.86	3.54	7.6	0.8	10	2.26	280	180	98	138	30	PCO+	
28	22	UM	4	158	74	29.6	124/82	98	96	110	0.87	9	0.09	10	5.4	1.85	3.4	13.2	4.9	8.6	2.4	288	168	100	138	32	PCO+	
29	26	M	4	154	68	28.7	120/80	96	84	110	0.76	9	0.11	14	5	2.80	2.8	13	0.7	4.7	2.4	260	178	100	138	28	PCO+	
30	28	M	4	165	50	18.4	124/82	74	96	80	1.20	9	0.09	12	5	2.40	3.8	13	0.8	19	0.7	290	178	88	118	36	PCO+	
1	12	UM	8	160	62	24.2	120/80	86	86	110	0.78	12	0.14	8.6	4.2	2.05	3.1	8.7	1	9	1.5	260	172	90	110	34		
2	24	UM	8	164	65	24.2	120/70	86	90	100	0.90	3.5	0.04	9.6	4.2	2.29	3.1	14	1	18.1	1.5	213	174	115	133	34		
3	22	UM	8	158	70	28	110/70	94	84	102	0.82	13.1	0.16	11.6	5	2.32	4	9.2	1.1	9	2.24	300	170	94	126	34		
4	22	UM	8	160	59.3	23.2	110/70	84	70	90	0.78	9.8	0.14	8.6	5.3	1.62	2.3	7.5	1.1	6.3	3.6	350	192	90	120	40		
5	26	UM	8	148	54	24.7	100/70	87	92	120	0.77	7.6	0.08	10.4	4.3	2.42	2.5	7.5	0.6	9.8	2.9	320	220	136	156	36		
6	22	UM	8	165	46	16.9	110/70	72	90	80	1.13	9.8	0.11	8.4	6	1.40	3.06	11.2	0.8	10.8	0.4	280	178	89	112	36		
7	23	UM	8	168	70	24.8	110/70	87	90	110	0.82	8.8	0.10	8.1	3.9	2.08	3.5	11.6	4.3	10.14	2.25	280	178	98	134	36		
8	22	UM	8	170	66	22.8	120/80	84	78	103	0.76	9.2	0.12	9.4	6	1.57	2.3	13.2	0.9	7.8	3.2	211	168	98	102	36		
9	20	UM	8	159	62	24.5	110/70	87	82	118	0.69	11	0.13	9.6	5.2	1.85	3.1	15.2	0.9	24.6	3.2	260	168	138	142	36		
10	22	UM	8	154	67	28.3	110/70	94	86	110	0.78	12	0.14	10.2	4.6	2.22	2.3	9	0.7	8	3	268	224	86	90	34		
11	24	UM	8	165	49.5	18.2	110/70	74	78	110	0.71	9.6	0.12	8.3	4.2	1.98	2.3	12.3	0.7	8.6	3	265	218	88	98	36		
12	24	M	8	165	73	26.8	110/80	92	99	104	0.95	15	0.15	10.6	4.6	2.30	4.1	10.2	1.1	20.6	1.8	258	230	102	170	38	PCO+	

Patient ID	Age	MS	Wks	HT	WT	BMI	BP	AC	FBS	PPBS	FBS/PPBS	F.I	I/G	LH	FSH	LH/FSH	TSH	PRO	T.Testo	F. Testo	Serum Andro	DHEAS	TC	TGL	LDL	HDL	USG	PI
13	26	M	8	152	62	26.8	140/90	92	90	114	0.79	10	0.11	8.1	4	2.03	3.6	10.3	0.5	8	2.1	278	250	158	168	34	PCO+	
14	28	M	8	164	50.3	18.7	230/70	76	73	93	0.78	7	0.10	12.1	4.6	2.63	3.3	15.6	1.04	4	3.8	300	158	74.3	84.3	62	PCO+	
15	30	M	8	151	38	16.7	130/80	72	76	100	0.76	7.6	0.10	9.6	4.1	2.34	2.8	9.6	0.9	5.5	3	258	168	148	140	34	PCO+	
16	28	M	8	162	73	27.8	130/70	94	92	110	0.84	12	0.13	9.2	4.6	2.00	4	11.6	0.9	9	4.4	640	230	120	152	44	PCO+	
17	26	M	8	164	60	22.3	140/90	82	64	79	0.81	5.6	0.09	8.6	4.3	2.00	2.1	11	0.6	17.5	1.5	210	178	98	138	36	PCO+	
18	24	M	8	158	57	22.8	130/80	84	106	90	1.18	15	0.14	8.3	4.4	1.89	1.8	4.7	0.5	8	1.7	160	216	86	96	38	PCO+	
19	24	M	8	172	64	21.6	126/80	82	82	92	0.89	5.6	0.07	9.6	4.2	2.29	2.62	16.3	0.1	9	2.1	198	168	98	102	36	PCO+	
20	28	M	8	156	47	19.3	130/90	76	82	90	0.91	8.6	0.10	7.2	5	1.44	2.7	10.2	0.16	6	2.2	200	164	134	136	32.3	PCO+	
21	24	M	8	154	60	25.3	120/80	87	90	100	0.90	6.4	0.07	8.4	4.2	2.00	4	8.4	0.9	9	2.26	300	186	82	104	34	PCO+	
22	22	M	8	158	68	27.2	120/80	92	90	100	0.90	10.2	0.11	6.4	4.8	1.33	3.3	12.4	1.04	8.8	2.2	358	170	94	136	38.4	PCO+	
23	26	M	8	148	54	24.7	110/70	87	90	110	0.82	8.6	0.10	7.4	5	1.48	3.2	6.8	0.6	4.9	2.8	260	222	134	158	42	PCO+	
24	28	M	8	170	66	22.8	130/80	84	82	98	0.84	9.2	0.11	7.2	4.4	1.64	2.4	7.8	1.04	5.6	2.24	214	174	92	134	37.2	PCO+	
25	30	M	8	160	64	25	130/80	87	88	110	0.80	9.6	0.11	10.6	5.4	1.96	3.2	16	1.5	20	2.26	290	186	96	118	37	PCO+	
26	30	M	8	168	72	25.5	140/100	90	92	117	0.79	9	0.10	12	4.1	2.93	2.24	10	1.4	19	2.24	280	178	98	138	36	PCO+	
27	20	UM	8	170	64	22.1	132/92	82	92	118	0.78	17	0.18	12	4.8	2.50	3.5	7.4	0.8	10.4	2.26	280	178	98	138	30	PCO+	
28	22	UM	8	158	73	29.2	120/80	96	84	110	0.76	9	0.11	9.6	5.2	1.85	3.4	12.8	4.9	8.6	2.4	287	168	100	136	32	PCO+	
29	26	M	8	154	66	27.8	120/70	94	80	110	0.73	9	0.11	12.6	5	2.52	2.8	12.6	0.7	5	2.4	260	178	100	138	30	PCO+	
30	28	M	8	165	50	18.4	120/80	74	90	72	1.25	10	0.11	10.6	4.2	2.52	3.7	12.4	0.8	19	0.7	290	178	88	118	36	PCO+	
1	12	UM	12	160	60	23.4	120/80	84	84	108	0.78	7	0.08	6.4	5.2	1.23	3.14	6.2	1	6.2	2.5	252	160	82	110	34	CYC.REG	
2	24	UM	12	164	65	24.2	110/70	86	88	106	0.83	3.5	0.04	8.1	5.1	1.59	3.2	12.1	1	10.4	1.53	210	169	110	125	34		
3	22	UM	12	158	68	27.2	110/70	92	84	106	0.79	8.1	0.10	8.1	5.2	1.56	4.1	7.2	1	5.3	2.24	238.3	172	90	124	34	CYC.REG	
4	22	UM	12	160	58.3	22.8	110/70	84	66	94	0.70	9.8	0.15	8.2	4.2	1.95	2.3	7.4	1.18	6.3	3.6	320	184	84.2	118	42		
5	26	UM	12	148	50	22.8	90/70	84	90	110	0.82	7.6	0.08	7.3	4	1.83	2.4	7.4	0.5	8.6	2.9	290	220	134	156	38	CYC.REG	
6	22	UM	12	165	45	16.5	100/70	72	90	84	1.07	9.8	0.11	6.2	6.8	0.91	3.07	10.02	0.8	7.3	0.4	264	175	89	110	36		
7	23	UM	12	168	70	24.8	100/70	87	94	112	0.84	8.6	0.09	8.1	4.3	1.88	3.6	10.2	4.3	7.1	2.26	272	176	96	132	36		
8	22	UM	12	170	66	22.8	110/70	84	80	104	0.77	8.6	0.11	7.2	5.2	1.38	2.2	11.4	0.9	6.2	3.2	206	168	98	102	38		
9	20	UM	12	159	62	24.5	110/70	87	90	110	0.82	8.3	0.09	6.2	5	1.24	3.1	11.2	0.8	16	3.2	258	166	136	140	35		
10	22	UM	12	154	63	26.6	110/70	92	90	112	0.80	10.6	0.12	10	4	2.50	2.3	7.3	0.7	6	3.1	263	220	84	88	34		
11	24	UM	12	165	48	17.6	120/70	74	76	110	0.69	8	0.11	8.4	4	2.10	2.3	11.2	0.7	7	3	257	216	86	98	36		
12	24	M	12	165	69	25.3	110/70	87	98	84	1.17	10.2	0.10	9.2	4.8	1.92	4.1	8.4	1.1	10.2	1.8	240	228.4	100	169	38	PCO+	
13	26	M	12	152	60	26	140/90	90	96	110	0.87	9.8	0.10	7.2	3.8	1.89	3.6	10.6	0.5	6.1	2.1	262	241	151	132	36	PCO+	
14	28	M	12	164	50.3	18.7	130/70	76	84	93	0.90	6.8	0.08	8.6	4	2.15	3.2	13.2	1.04	3.8	3.8	280	156.2	74	84.3	62	PCO+	
15	30	M	12	151	38	16.7	130/80	72	82	96	0.85	7	0.09	8.4	3.6	2.33	2.8	9.2	0.9	5.3	3	243	166	147	140	34	PCO+	
16	28	M	12	162	72	27.4	120/80	92	94	114	0.82	10.6	0.11	8.2	4	2.05	4	9.8	0.9	7.3	4.3	600	228	118	150	44	PCO+	
17	26	M	12	164	60	22.3	130/80	82	69	84	0.82	5.3	0.08	7.3	4	1.83	2.1	10.2	0.6	10.3	1.53	183	176	96	136	36	PCO+	
18	24	M	12	158	56	22.4	130/80	82	84	96	0.88	12.1	0.14	6.2	4.2	1.48	1.8	4.7	0.6	4.3	1.7	150	210	86	96	38	GES.SAC	
19	24	M	12	172	62	21	126/82	80	76	84	0.90	5.4	0.07	7.1	4	1.78	2.6	14.2	0.1	6.2	2.1	186	166	98	102	38	GES.SAC	

Patient ID	Age	MS	Wks	HT	WT	BMI	BP	AC	FBS	PPBS	FBS/PPBS	F.I	I/G	LH	FSH	LH/FSH	TSH	PRO	T.Testo	F. Testo	Serum Andro	DHEAS	TC	TGL	LDL	HDL	USG	PI	
20	28	M	12	156	48	19.7	130/80	78	76	94	0.81	8.6	0.11	6.1	4.8	1.27	2.7	10	0.16	4.3	2.24	201	164	134	136	34.3	GES.SAC		
21	24	M	12	154	58	24.5	120/80	87	96	88	1.09	6.3	0.07	7	4	1.75	4	7.6	0.9	6	2.26	259	183	80	100	34.2	GES.SAC		
22	22	M	12	158	66	26.4	122/82	90	96	88	1.09	7.6	0.08	5.8	4.6	1.26	3.4	10.3	1.04	6	2.24	248	170	94	136	38	GES.SAC		
23	26	M	12	148	52	23.7	110/70	86	92	123	0.75	8.4	0.09	6.1	5.2	1.17	3.2	6.1	0.6	4	2.8	210	222	132	158	45	GES.SAC		
24	28	M	12	170	66	22.8	120/80	84	90	106	0.85	8	0.09	6	3.9	1.54	2.4	7.6	1.04	3.8	2.24	200	170	90	134	38	GES.SAC		
25	30	M	12	160	64	25	120/80	87	80	92	0.87	9.4	0.12	8.4	5.2	1.62	3.2	15.2	1.5	10.2	2.26	264	186	96	116	37	PCO+		
26	30	M	12	168	70	24.8	140/90	87	90	110	0.82	8.8	0.10	10.2	3.8	2.68	2.24	9.8	1.4	12.2	2.26	276	174	94	136	36	PCO+		
27	20	UM	12	170	63	21.8	140/90	82	90	124	0.73	17	0.19	11.6	4.2	2.76	3.5	7.4	0.8	10.2	2.26	274	178	96	136	32	PCO+		
28	22	UM	12	158	73	29.2	120/80	96	84	110	0.76	8.6	0.10	9.4	5	1.88	3.4	4.3	4.9	8.4	2.4	280	164	102	136	34	PCO+		
29	26	M	12	154	66	27.8	120/80	94	90	110	0.82	8.8	0.10	12	5.8	2.07	2.7	12	0.7	5.6	2.4	259	176	98	136	32	PCO+		
30	28	M	12	165	52	19.1	120/70	76	96	80	1.20	9.1	0.09	10.8	4	2.70	3.7	12	0.8	17.6	0.7	280	176	84	116	38	PCO+		
1	12	UM	16																										
2	24	UM	16	164	64	23.8	110/70	86	102	110	0.93	3.5	0.03	6.2	5.4	1.15	3.2	11.2	1	5.2	1.3	200	164	110	120	34		CYC.REG	
3	22	UM	16																										
4	22	UM	16	160	58.3	22.8	110/80	84	64	90	0.71	9.1	0.14	7.6	5	1.52	2.3	7	1.18	6.3	3.6	270	184	82.6	178	42		CYC.REG	
5	26	UM	16	148	49	22.4	90/70	82	92	124	0.74	7.5	0.08	6.4	4.20	1.52	2.50	7.20	0.60	5.4	2.9	270	220	134	154	38			
6	22	UM	16	165	45	16.5	100/70	72	94	84	1.12	9	0.10	5.4	6	0.90	3.05	8.25	0.8	5.8	0.4	252	170	86	100	36		CYC.REG	
7	23	UM	16	168	68	24.1	120/80	86	92	120	0.77	8.2	0.09	6.2	4.6	1.35	3.6	9.6	4.3	6.2	2.26	251	176	96	132	36		CYC.REG	
8	22	UM	16	170	65	22.5	110/70	84	90	106	0.85	8	0.09	6.6	7	0.94	2.2	10.2	0.9	5.4	3.2	206	168	98	104	38		CYC.REG	
9	20	UM	16	159	60	23.7	120/80	86	80	120	0.67	6.4	0.08	5.2	6.2	0.84	3.2	10	0.8	10.2	3.2	250	166	136	140	46		CYC.REG	
10	22	UM	16	154	62	26.1	100/70	90	90	118	0.76	10	0.11	9.2	5.6	1.64	2.3	7	0.7	6	3.1	263	220	84	88	34			
11	24	UM	16	165	48	17.6	110/70	74	76	110	0.69	8	0.11	7.6	4.2	1.81	2.4	10.6	0.7	7	3	257	216	86	100	36			
12	24	M	16	165	66	24.2	110/70	86	90	73	1.23	8	0.09	7.2	4.4	1.64	4.1	6.2	1	7.1	1.8	232	220	100	162	38	GES.SAC		
13	26	M	16	152	58	25.1	130/80	87	88	112	0.79	7.4	0.08	6.6	4.1	1.61	3.6	9.9	0.5	4.2	2	241	232	147	112	36	GES.SAC		
14	28	M	16	164	51.2	19	130/70	76	82	96	0.85	6.8	0.08	7	3.9	1.79	3.2	12.3	1	3.05	3.8	266	156.2	72.6	84.2	62.3	GES.SAC		
15	30	M	16	151	40	17.5	130/80	74	82	96	0.85	6.8	0.08	7.2	3.8	1.89	2.8	8.2	0.9	5.2	3	220	166	147	138	34	GES.SAC		
16	28	M	16	162	70	26.7	120/80	92	96	114	0.84	8.2	0.09	7	4.4	1.59	4	6.2	0.9	6.2	4.3	584	228	118	150	44	GES.SAC		
17	26	M	16	164	60	22.3	130/90	82	70	84	0.83	5.3	0.08	6.2	4.2	1.48	2.1	9.2	0.6	6.2	1.5	162	176	96	136	36	GES.SAC		
18	24	M	16																										
19	24	M	16																										
20	28	M	16																										
21	24	M	16																										
22	22	M	16																										
23	26	M	16																										
24	28	M	16																										
25	30	M	16	160	62	24.2	120/70	86	84	100	0.84	9.4	0.11	7.1	5.1	1.39	3.4	15	1.5	10.2	2.26	264	184	94	116	38	PCO+		
26	30	M	16	168	70	24.8	140/92	87	92	110	0.84	8.6	0.09	9.6	4.2	2.29	2.24	8.4	1.4	12	2.26	276	174	94	136	38	PCO+		

Patient ID	Age	MS	Wks	HT	WT	BMI	BP	AC	FBS	PPBS	FBS/PPBS	F.I	I/G	LH	FSH	LH/FSH	TSH	PRO	T.Testo	F. Testo	Serum Andro	DHEAS	TC	TGL	LDL	HDL	USG	PI	
4	22	UM	24																										
5	26	UM	24																										
6	22	UM	24																										
7	23	UM	24																										
8	22	UM	24																										
9	20	UM	24																										
10	22	UM	24																										
11	24	UM	24																										
12	24	M	24																										
13	26	M	24																										
14	28	M	24																										
15	30	M	24																										
16	28	M	24																										
17	26	M	24																										
18	24	M	24																										
19	24	M	24																										
20	28	M	24																										
21	24	M	24																										
22	22	M	24																										
23	26	M	24																										
24	28	M	24																										
25	30	M	24																										
26	30	M	24																										
27	20	UM	24	170	60	20.8	130/80	80	92	124	0.74	16	0.17	10.2	4.2	2.43	3.6	7	0.8	9.6	2.26	274	180	98	134	32	PCO+		
28	22	UM	24	158	70	28	120/80	94	96	126	0.76	8	0.08	9.6	4.2	2.29	3.3	11.2	4.8	8	2.3	274	164	98	134	34	PCO+		
29	26	M	24	154	65	27.4	120/70	94	90	118	0.76	8	0.09	10.2	5.9	1.73	2.7	11.8	0.7	4.2	2.4	248	176	98	136	32	PCO+		
30	28	M	24	165	50	18.4	110/70	74	96	86	1.12	8.6	0.09	10	5.9	1.69	3.8	10.9	0.8	12.3	0.8	273	174	84	116	40	PCO+		

CASE SHEET

Registration no:

Date:

Name:

Age:

Sex:

Address:

Phone no:

Occupation:

Marital Status:

Weight (Kg):

Height (Cm):

BMI:

Abdominal circumference:

Waist hip ratio:

Complaints:

H/o Present illness:

Past History

Personal History:

Family History:

Menstrual History:

Obstetric History:

General Examination:

Patients conscious oriented pallor cyanosis clubbing pedal edema

generalised lymphadenopathy Hirsutism Virilism

Breast Examination

Thyroid Examination

BP:

PR:

RR:

Systemic examination:

Investigation:

COMPLETE HAEMOGRAM:	BASELINE	4 th week	8 th week	12 th week	16 th week	20 th week	24 th week
Fasting Glucose							
Fasting Insulin							
Insulin to Glucose Ratio							
HORMONAL PROFILE:							
LH							
FSH							
LH/FSH Ratio							
TSH							

Prolactin							
Serum Total Testosterone Free Testosterone							
Serum Androstenedione							
Serum DHEA-S							
LIPID PROFILE							
Total Cholesterol							
TGL							
LDL							
HDL							
LDL/HDL Ratio							
VLDL							

USG Findings:

Treatment:

Signature of Investigator

CONSENT FORM

(To be obtained from subject)

Introduction:

I,..... is willing to participate in a study conducted in **department of Pharmacology**, Chennai Medical College Hospital & Research Centre, Irungalur, Tiruchirapalli, Tamil Nadu entitled.

“EVALUATION OF EFFICACY AND SAFETY OF MYOINOSITOL IN WOMEN WITH POLYCYSTIC OVARIAN SYNDROME TREATED AT A TERTIARY CARE HOSPITAL”

My participation in this study is Voluntary. I am at liberty to participate/ withdraw from the study. I have read this consent form carefully and ask the Consultant, questions I may have about the study before signing.

Explanation of Procedure:

By agreeing to participate in this study, I know that the investigator will ask some question to me and collect relevant information/ Blood sample/Body fluids and perform Ultra sound abdomen scan. I may be examined by the investigator and I am willing to take the tablets given by the investigator. Data from the study will be used for research purposes only. The results of the study will not to be given to me directly. There will be no cost to me participating in this study.

Potential benefits:

My participation will help the investigator to know the risk factor of this problem and results of this study will be beneficial for future generations.

Assurance of Confidentiality:

The information concerning my participation in the study will be kept confidential to the full extent permitted by law and used only for scientific purposes. No one except members of the research team will have access the results. My name will not be disclosed in any report or released in any way.

Patient Consent:

I have read the explanation about this study and have been given an opportunity to discuss it and to ask questions. I have not received any money for participating in this study.

Signature of Subject

Signature of Witness

Date

Signature of Researcher

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