TITLE OF THE ABSTRACT: Montelukast for acute asthma exacerbation in children aged 5 years -15 years- A randomized double blind placebo controlled study

DEPARTMENT: Pediatrics

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OBJECTIVES: To compare the effect of montelukast with placebo when combined with standard treatment of mild to moderate exacerbation of asthma by measuring modified pulmonary index score, PEFR and subjective improvement on a visual analog scale at 4 hours and 36-48 hours after intervention.

METHODOLOGY: Randomised double blinded, placebo controlled study was done in 2015 on children aged 5-15 years who presented with mild to moderate exacerbation of asthma, comparing the outcome measures when montelukast (2 doses, 24 hours apart) or placebo was combined with standard treatment. The primary outcome studied was Modified Pulmonary Index Score (MPIS) reduction from baseline to 4 hours. Secondary outcomes studied were comparison of PEFR and visual analog scale at 4 hours and 36-48 hours and MPIS at 36 hours. The need for steroid use in both groups were compared. The sample size was calculated to be 52 in each group. Data was analysed using SPSS software. The proportions among the two groups were compared using Chi square test. Independent student t test was used to measure the mean difference in the continuous variables.

RESULTS: Interim analysis of the data was done when 22 children were enrolled, 11 were in montelukast and 11 in placebo arm. The baseline characteristics between the two groups were similar. Interim analysis did not show statistically significant difference between montelukast and placebo in the parameters assessed namely reduction in MPIS, peak expiratory flow rate, visual analog scale at 4 hours and after 36 hours. However, children in montelukast group showed a trend towards better outcome in all parameters assessed.

Keywords: Montelukast, Modified pulmonary index score, Peak expiratory flow rate, Visual analog scale