

**Project No:** 4048/2010

**ROLE OF H1 AND H2 ANTIHISTAMINICS FOR REDUCTION OF INHALED STEROIDS IN CHILDHOOD ASTHMA**

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**OBJECTIVES**

1. To determine the extent to which H1 and H2 antihistaminic reduce the symptoms of asthmatics
2. To determine whether usage of H1 and H2 antihistaminic can result in replacing or reducing the dose of inhaled corticosteroids in childhood asthma

**METHODOLOGY**

This was a randomized open-label study conducted at a zonal hospital from 15 Oct 2010 to 31 Mar 2011. The study population comprised of children 4 to 12 years old with physician diagnosed moderate to severe asthma. All participants received salmeterol Meter Dose Inhaler (MDI) 50 mcg BID and Fluticasone MDI 125 mcg BID (Seroflow, Cipla Inc) throughout the run in and post randomization periods, during the run-in, participants demonstration evidence of inadequate control on ICS plus salmeterol, with subsequent documentation that step-up to a higher dose of ICS (to a maximum of 750 mcg Fluticasone daily, again with salmeterol) established control. In the second phase, the patients were randomized to receive a combination of Cetirizine (5mg PO qd for children <6 years; 10 mg PO qd for children  $\geq$  6 years) and Ranitidine (10mg/kg/day, PO qd). Once daily at night, or placebo. Following randomization, participants received the dose of ICS that achieved control in addition to salmeterol BID for an additional four weeks, along with the interventional drugs/placebo. During the third phase of trial, the patients proceeded through three one-week period of ICS reduction, first to 75% of the control dose ("0.75X"), then 50% of the control dose ("0.5X") and then 25% of the control dose ("0.25X"), each using salmeterol 50 mcg BID as concomitant medication. After the lowest dose was achieved and control maintained for an additional 2 week, the MDI was withdrawn, the patient maintained on either the interventional oral drugs or placebo, and follow-up was continued for an additional 8 weeks. The primary outcome was duration of adequate asthma control measured as time (in weeks) to inadequate asthma control.

**RESULTS**

Of the 126 children randomized, 65 were in the interventional group and 61 were in the control group. Among the 65 children receiving antihistamines, 14/65 (21.5%) remain controlled until the last visit, while the remaining had recurrence of symptoms. Among the patients receiving placebo, 11/61 (18%) were controlled until the last visit. The administration of antihistamines did not offer any protection ( $p=0.45$ , Hazard Ratio=1.19, 95% confidence interval=0.76 to 1.88). However, the patient with allergic rhinitis who received antihistamines ( $n=18$ ) had better controlled symptoms ( $p=0.01$ , HR=3.94; 95% CI=1.37 to 11.35).

**CONCLUSION**

Antihistamines are beneficial for controlling symptoms only in patients with co-existent bronchial asthma and allergic rhinitis. In patients with bronchial asthma without concomitant allergic rhinitis, antihistamines were no better than placebo.