



A Randomized Open-Label Comparative Study of Montelukast versus Theophylline Added to Inhaled Corticosteroid in Asthmatic Children

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Background: Inhaled corticosteroids (ICSs) are widely used in combination with other classes of drugs for treatment of childhood asthma. The efficacy and the safety of montelukast added to low-dose ICS therapy were compared with those of sustained-release theophylline added to low-dose ICS therapy in asthmatic children in the present study.

Methods: Following the 2-week run-in period, 6-to 14-year old patients receiving treatment with ICSs were randomized to treatment for 4 weeks with either montelukast 5 mg once daily or sustained release theophylline 5—8 mg/kg (dry syrup) or 100—200 mg (tablet) twice daily. Patients also received a fixed dose of ICS throughout the run-in and treatment periods. The primary efficacy endpoint was the change from baseline in peak expiratory flow (PEF) at Week 2.

Results: A significant increase in morning PEF was observed in the add-on montelukast group as compared with the add-on theophylline group at Week 2 (change from baseline of 22.8 L/min vs. 8.7 L/min; $p = 0.041$ for between-group difference) and at Week 4 (31.0 L/min vs. 9.8 L/min; $p = 0.012$). A significant increase in evening PEF was observed in the add-on montelukast group as compared with the add-on theophylline group at Week 4 (24.7 L/min vs. 8.7 L/min; $p = 0.027$). There were no significant differences between the treatment groups in incidences of clinical and laboratory adverse experiences.

Conclusions: The results indicate that montelukast added to low-dose ICS is an effective and safe option for the treatment of asthma in children.

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