

it was worth investigating whether it would have additive benefit for acute asthma, but this study found that it does not.

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John M. Kelso, MD
San Diego, CA

The Back to School Asthma Study: The Effect of Montelukast on Asthma Burden When Initiated Prophylactically at the Start of the School Year

Weiss KB, Gern JE, Johnston NW, et al. *Ann Allergy Asthma Immunol.* 2010;105(2):174-181

PURPOSE OF THE STUDY. To determine the efficacy of prophylactic montelukast therapy in reducing asthma morbidity at the start of the school year.

STUDY POPULATION. Patients 6 to 14 years of age with a diagnosis of asthma for a minimum of 1 year were recruited for this international study that took place in 39 US states and 3 Canadian provinces from June 2006 through November 2006.

METHODS. This was a randomized, multicenter, double-blind, placebo-controlled study for patients who received either 5-mg montelukast or placebo beginning on the night before school started and continued for an 8-week period. Patients were randomly assigned during a screening period from 2 to 12 weeks before the school start date. Patients were interviewed by telephone to review symptoms, use of study medications, and need for additional β agonists 4 weeks after starting school. A final study visit at 8 weeks was conducted to document daytime symptoms, "awake all night," inhaled corticosteroid use, increased β -agonist use, and visits to a health care professional or facility for asthma. Inclusion criteria included treatment of asthma within 6 months of screening and patients having at least 1 exacerbation of asthma symptoms in the previous year that were associated with a cold. Exclusion criteria included forced expiratory flow volume in 1 second below 60% of that predicted, use of systemic steroids within 4 weeks of randomization, and more than 3 hospitalizations for asthma in the previous year. Patients on treatment with a long-acting β agonist or leukotriene receptor antagonist within 10 days of randomization were also excluded.

RESULTS. Of 1162 patients (580 randomly assigned to the montelukast group and 582 randomized to the placebo group), no significant difference was seen for the percentage of days with worsening asthma. A trend for montelukast to reduce worsening asthma days in those who began school after August 15 was seen but was not significant. A nonsignificant trend in older children and boys favoring treatment with montelukast was also seen.

CONCLUSIONS. The use of montelukast did not significantly reduce the number of days with worsening asthma when begun as prophylactic therapy at the start of the school year.

REVIEWER COMMENTS. The start of the school year presents a challenge for asthmatic children, who have greater disease burden with respiratory illnesses. In the group of children treated with montelukast, the percentage of days with worsening asthma was stable, whereas this percentage increased in weeks 3 to 4 in the placebo group and subsequently decreased for the remainder of the study. Because this study did not answer the need to prevent morbidity from asthma during the fall, additional studies are needed to address this concern.

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Vivian Hernandez-Trujillo, MD
Miami, FL

Combination Therapy Salmeterol/Fluticasone Versus Doubling Dose of Fluticasone in Children With Asthma

Vaessen-Verberne AA, van den Berg NJ, van Nierop JC, et al; COMBO Study Group. *Am J Respir Crit Care Med.* 2010;182(10):1221-1227

PURPOSE OF THE STUDY. To determine if the addition of a long-acting bronchodilator is noninferior to doubling the dose of inhaled corticosteroids in children whose asthma is not controlled with use of low-to-moderate doses of inhaled corticosteroids alone.

STUDY POPULATION. Children aged 6 to 16 years who were using fluticasone propionate (100 μ g twice daily) to treat their asthma were enrolled in this study ($N = 257$). A 4-week run-in period was used to monitor these children. Those who were still symptomatic despite regular use of fluticasone propionate were included in the randomization of study groups ($n = 158$). The study was conducted at multiple pediatric medical centers throughout Europe.

METHODS. Symptomatic children were randomly assigned to 1 of 2 treatment groups: fluticasone propionate (200 μ g twice per day) or salmeterol/fluticasone propionate (50/100 μ g twice per day), used for a 26-week treatment period. Lung-function measurements were recorded at the start of the run-in period, at time of randomization, and at all visits during the treatment period. The provocative dose of methacholine that causes a 20% decrease (PD_{20}) in the forced expiratory volume in 1 second (FEV_{1}) and exhaled nitric-oxide levels were measured at the start and end of the treatment period. The number of symptom-free days and asthma exacerbations were logged at each clinic visit. Exacerbations were classified as mild, moderate, or severe on the basis of the medical interventions needed.

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Vivian Hernandez-Trujillo

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