MEDICAL THERAPIES

Daily Versus As-Needed Corticosteroids for Mild Persistent Asthma


PURPOSE OF THE STUDY. To determine the effectiveness of as-needed versus regular controller therapy in adults with mild persistent asthma.

STUDY POPULATION. A total of 225 adults with symptom criteria for mild persistent asthma and forced expiratory volume in 1 second (FEV₁) >70% predicted with >12% reversibility or PC₂₀ (provocative concentration causing a 20% decrease in FEV₁) methacholine at ≤16 mg/mL.

METHODS. Patients were assigned to 1 of 3 treatment groups: budesonide DPI 200 µg twice daily (BUD), oral zafirlukast 20 mg twice daily (ZAF), or placebo. The study was double-blind, double-dummy. At the beginning and the end of the study, all patients were treated with 0.5 mg/kg per day of prednisone, 800 µg twice a day of budesonide, and 20 mg twice a day of zafirlukast plus as-needed albuterol. Evaluation was accomplished by assessing asthma symptoms followed by pulmonary-function testing and gathering information on, albuterol use and exacerbations over the 1-year study.

RESULTS. For both of the primary efficacy outcomes, morning peak expiratory flow rate and exacerbations, there were no differences between the groups. Several outcomes were superior for the BUD group, including prebronchodilator FEV₁, bronchial reactivity, symptom scores, exhaled nitric oxide, asthma control score, and symptom-free days (26 more). Postbronchodilator FEV₁ and quality of life were not different between the groups. The as-needed group took budesonide, on average, for only one-half week during the study.

CONCLUSIONS. Adults with mild persistent asthma can be managed with high-dose budesonide on an intermittent basis. However, greater improvement in markers of airway inflammation and more symptom-free days (26 per year) occurred with regular use of low-dose budesonide.

REVIEWER COMMENTS. This is an adult study that focused on short-term outcomes, which may not translate to children. It is not known if similar results would be seen with a longer-term study.

Safety of Budesonide Inhalation Suspension in Infants Aged Six to Twelve Months With Mild to Moderate Persistent Asthma or Recurrent Wheeze


PURPOSE OF THE STUDY. To compare the safety of budesonide inhalation suspension (BIS) with placebo.

STUDY POPULATION. Infants (aged 6–12 months) with mild-to-moderate persistent asthma or recurrent wheeze.

METHODS. A multicenter, randomized, double-blinded, parallel-group, placebo-controlled study, in which 141 infants received 0.5 mg of BIS (n = 48), 1.0 mg of BIS (n = 44), or placebo (n = 49) once daily for 12 weeks. The primary variable was adrenal function, which was based on cosyntropin-stimulated plasma cortisol levels. Spontaneous adverse events and clinical laboratory findings were monitored.

RESULTS. Overall, the types and frequencies of adverse events reported during the study were comparable across treatment groups. The response to cosyntropin stimulation was similar across treatment groups, with no significant difference between BIS treatment and placebo.

CONCLUSIONS. The safety profile of BIS was similar to that of placebo, with no suppressive effect on adrenal function in patients 6 to 12 months of age with mild-to-moderate persistent asthma or recurrent wheeze.

REVIEWER COMMENTS. Inhaled corticosteroids remain the preferred choice for the long-term management of persistent asthma in pediatric patients. In addition, because BIS has become available for clinical use, more and more infants and young children with persistent asthma and/or recurrent episodes of wheezing have been managed with this inhaled antiinflammatory medication. In turn, appropriate questions have arisen from caregivers and providers about the overall safety of this therapy in these very young patients. Although the safety and efficacy of nebulized BIS have been confirmed in well-designed investigations in patients 6 months to 8 years of age, controlled clinical studies addressing the safety and efficacy of inhaled corticosteroids exclusively in the infant age range have been lacking. This current investigation provides very useful safety data for BIS in this understudied infant population. The data demonstrate that once-daily administration of BIS, 0.5 or 1.0 mg, was not associated with a decrease in adrenal function, which was based on cosyntropin-stimulated plasma cortisol levels. This information should be very useful to health care providers who prescribe this medication for
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