



Frank Petruzella, MD
Recipient of the Ken Graff Young Investigator Award
American Academy of Pediatrics
2008 National Conference & Exhibition

A Randomized, Double Blind, Placebo Controlled Trial of Daily Montelukast for the Treatment of Viral Bronchiolitis

A study proposal

*For the American Academy of Pediatrics, Section on Emergency Medicine,
Ken Graff Young Investigator Grant Program*

Background:

Although viral bronchiolitis is the most common cause of hospitalization in infants under 2 years of age, there continues to be no therapy that consistently reduces the severity or duration of the illness. Infants with bronchiolitis have increased levels of cysteinyl leukotrienes (cysLTs) in nasal lavage and bronchoalveolar lavage (BAL) samples. CysLTs have been shown to increase airway edema and hyperresponsiveness, contributing to obstruction of small airways. Administration of cysLT modifiers in animal and *in vitro* models of bronchiolitis has decreased both severity and duration of symptoms.

Objective:

To evaluate the effect of daily montelukast (a cysLT receptor antagonist) on symptom duration in infants with first-time bronchiolitis evaluated in the Emergency Department (ED).

Hypothesis:

Administration of daily montelukast will shorten symptom duration when compared to placebo.

Methods:

This will be a randomized, double-blind, placebo-controlled trial of montelukast given daily for treatment of viral bronchiolitis. Eligible infants will be 3 to 12 months old, have a clinical diagnosis of bronchiolitis, and have no history of previous wheezing illness, prior bronchodilator or corticosteroid use, immunosuppression, or a diagnosis of croup or pneumonia. Baseline demographic, clinical, and historical data will be collected at enrollment, and subjects will be randomized to receive 4mg montelukast or placebo daily for 14 days or until asymptomatic. Weekly telephone interviews will be used to assess duration and severity of cough in infants for six weeks or until asymptomatic. Also evaluated will be days of missed daycare, days of missed work by the caregiver, and unplanned medical visits after discharge.