Vitamin D to Prevent Severe Asthma Exacerbations (Vit-D-Kids Asthma)

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Background: Asthma is a major public health problem in the United States and worldwide. Severe disease exacerbations account for the majority of costs attributable to asthma in the United States. Vitamin D is an essential nutrient with significant immuno-modulatory effects. The observation that vitamin D deficiency and asthma share risk factors such as urban residence, obesity, and African American ethnicity has generated significant interest in exploring a link between these two conditions. We and others have shown an association between low circulating vitamin D levels and increased asthma severity, including increased risk of asthma exacerbations. Several small studies in children, have shown that vitamin D supplementation may reduce the risk of asthma exacerbations. These trials are inconclusive because of: inclusion of children with normal/unknown vitamin D level; no data on treatment or adherence; no/unknown occurrence of severe exacerbations; and low vitamin D dose.

Study objective: The purpose of this study is to determine whether 4,000 units of daily oral cholecalciferol reduces the incidence of severe asthma exacerbations in high-risk (so defined due to a recent exacerbation) children aged 6-14 years with vitamin D insufficiency.

Methods: This is a 48-week randomized, double-masked, controlled trial of vitamin D3 (4,000 IU/day) to prevent severe asthma exacerbations in 400 high-risk children (aged 6 to 14 years) who have vitamin D insufficiency (serum 25(OH)D <30 ng/ml) and are well-controlled on low-dose inhaled corticosteroid (ICS) at the end of a run-in period. After stratification by race/ethnicity and study site, participants will be randomized in a 1:1 ratio to either 4,000 IU/day of vitamin D3 or placebo and then monitored, through clinic visits and phone calls.

The primary specific aim is to determine whether high-dose vitamin D3 supplementation (4,000 IU/day) is superior to placebo in preventing severe asthma exacerbations in high-risk school-aged children who have vitamin D insufficiency and who are on ICS for mild to moderate persistent asthma.

The secondary specific aims are to determine whether, among high-risk school-age children with vitamin D insufficiency, vitamin D3 supplementation of 4000 IU/day is superior to placebo in: preventing severe asthma exacerbations resulting from viral infections and reducing the daily dose of ICS, as well as the average cumulative dose of ICS, by the end of the trial.

Inclusion criteria:
- 6 to 14 years old
- Physician-diagnosed asthma
- At least one severe asthma exacerbation in the previous year
- Use of asthma medications

Benefits to participants: Through provided asthma education and close monitoring, participants may have some improvement in their health. Compensation provided.

Benefits to referring doctors: The information collected will help the investigators and research team to advance the understanding of asthma and the role that vitamin D plays in this disease. It may also help to develop new research studies that may possibly help individuals diagnosed with asthma in the future.

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