

Steroid-based treatment may answer needs of pediatric EoE patients

December 19 2014

A new formulation of oral budesonide suspension, a steroid-based treatment, is safe and effective in treating pediatric patients with eosinophilic esophagitis (EoE), according to a [new study](#) in *Clinical Gastroenterology and Hepatology*, the official clinical practice journal of the American Gastroenterological Association. Eosinophilic esophagitis is a chronic immune system disease caused by a buildup of white blood cells in the lining of the esophagus. This build up, which is a reaction to food, allergens or acid reflux, can inflame or injure esophageal tissue.

"EoE patients struggle daily, as the damage to their esophagus makes swallowing and eating a formidable challenge," said Sandeep K. Gupta, MD, lead study author from Indiana University School of Medicine and Riley Hospital for Children, Indianapolis. "There is a dire need for a safe and effective EoE treatment, as currently, there are no FDA-approved treatments for this condition. Oral budesonide suspension demonstrated remarkable efficacy to reduce eosinophilic inflammation in our study, offering hope for EoE patients."

Researchers conducted a prospective, randomized, double-blind, placebo-controlled study to assess the effectiveness and safety of oral budesonide suspension—a new, proprietary, oral formulation of budesonide—in children and adolescents (ages 2-18) with EoE. Patients were randomly assigned to groups given placebo, low-dose, medium-dose or high-dose therapy for 12 weeks. At the end of 12 weeks, histologic (improved tissue) response was achieved in more than 50 percent of patients in the medium-dose group and in more than 90 percent of patients in the high-

dose group. Only 5.6 percent of patients in the placebo group experienced improved histologic response; there was no significant difference in percentages of responders between the low-dose and placebo groups. Oral budesonide suspension was safe at all doses and there were no serious drug-related adverse events.

While EoE patients experienced significant histologic response in the medium- and high-dose groups, [patients](#) in all four groups experienced comparable symptom responses. Further research is needed to assess this treatment's ability to improve symptoms.

Oral budesonide suspension is designed to coat the esophagus with budesonide in order to treat local eosinophilic inflammation. Budesonide—a glucocorticoid steroid—is the active pharmaceutical ingredient in several products approved by the U.S. FDA, including products for the treatment of pediatric and adult asthma, allergic rhinitis, chronic obstructive pulmonary disease and Crohn's disease.

More information: Gupta, Sandeep K., et al. Efficacy and Safety of Oral Budesonide Suspension in Pediatric Patients With Eosinophilic Esophagitis. *Clinical Gastroenterology and Hepatology* 2015; 13(1): 66-76.e5

Provided by American Gastroenterological Association

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