A randomized, double-blind, placebo-controlled, multicenter study to evaluate the safety, efficacy, and pharmacokinetics of budesonide extended-release tablets administered once daily in pediatic subjects aged 5 to 17 years with active, mild to moderative ulcerative colitis

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: Up to 18 years old
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- 5 to 17 years old - diagnosis of Ulcerative Colitis (UC) - weight is greater than 13.6 kg (30 pounds) - active UC of mild or moderate severity - see link to clinicaltrials.gov for complete inclusion criteria

Exclusion Criteria:

- current or prior diagnosis of Crohn's disease or indeterminate colitis - severe UC - not currently in an active phase or flare - prior gastrointestinal surgery, except appendectomy or hernia - see link to clinicaltrials.gov for complete exclusion criteria

Conditions & Interventions

Conditions:
Digestive & Liver Health
Keywords:
UC, Ulcerative Colitis

More Information

Description: The purpose of this research study is to test the safety and effectiveness of Budesonide in low and high dose extended- release tablets in pediatric participants with active, mild to moderate Ulcerative Colitis and to evaluate the level of budesonide that remains in the blood after taking it. Participants will be asked to take an oral (by mouth) form of Budesonide or a placebo once daily for 8 weeks. A placebo is a tablet that does not contain any active study drug (Budesonide).
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