

Ketotifen for Children With Functional Dyspepsia in Association With Duodenal Eosinophilia

NCT02484248

Status	RECRUITING
Phase	Phase 3
Sponsor	Craig A. Friesen, MD
Enrollment	40 participants

Key Eligibility Criteria

Inclusion (6)

- between the ages of 8 and 17 years, inclusive
- abdominal pain of at least 8 weeks duration and fulfilling symptom-based criteria for functional dyspepsia(5);
- previous endoscopy with biopsies demonstrating $\gt;20$ eosinophils/high powered field on duodenal mucosal biopsies;
- previous treatment with acid-reduction therapy and montelukast with a level 3 (as defined below)or lesser response;
- evidence of written parental permission (consent) and subject assent;
- ... and 1 more (see full listing online)

Exclusion (10)

- previous treatment with ketotifen;
- treatment with oral corticosteroids or oral cromolyn sodium in the 6 months prior to enrollment;
- any prior history of diabetes mellitus, cancer, chronic cardiac disease, respiratory disease, or renal disease requiring routine medical care;
- Pregnant/planning to become pregnant;
- Post-menarche females unwilling to use highly-efficacious contraception to prevent pregnancy;
- ... and 5 more (see full listing online)

Locations (1 total)

The Children's Mercy Hospital, Kansas City, Missouri, United States