A Study to Check the Safety of Dexlansoprazole and Learn if it Can Treat Symptomatic Nonerosive Gastroesophageal Reflux Disease in Children 2 to 11 Years Old

NCT02616302

Status	RECRUITING
Phase	Phase 2
Sponsor	Takeda
Enrollment	70 participants

Key Eligibility Criteria

Inclusion (6)

- In the opinion of the investigator, the participant (as age appropriate) and/or parent(s)/legal guardian is capable of understanding and complying with protocol requirements.
- Prior to any study-specific procedures being performed, the appropriate informed consent and the assent form(s) (as applicable) must be signed and dated by parent(s) or legal guardian and by the participant respectively, if appropriate.
- Has a medical history of symptoms of GERD for at least 3 months prior to Screening.
- Has met the eDiary qualification criteria as assessed by the PGSDD, defined as hurting or burning in the stomach, chest, or throat on at least 3 of any 7 consecutive days during the Screening Period.
- Has no evidence of erosive esophagitis (EE) according to the Los Angeles (LA) Classification of Esophagitis and, in the investigator's clinical judgment, the symptoms are suggestive of acid-related disease. A 24-hour pH-metry (with or without impedance) may be performed during Screening or within 6 months prior to Screening for similar symptoms as those identified during Screening if, in the investigator's judgment, this procedure would aid in the determination of whether the participant's symptoms are acid-related. An endoscopy performed within 1 week prior to signing screening informed consent and assent form (as applicable) is an acceptable replacement for the screening endoscopy if nonerosive GERD is confirmed, protocol-required biopsies were collected, and endoscopic pictures were obtained.

... and 1 more (see full listing online)

Exclusion (23)

- Has evidence of cardiovascular, pulmonary, central nervous system, hepatic, hematopoietic, renal, or metabolic disorder, severe allergy, asthma, or allergic skin rash that suggests any uncontrolled, clinically significant underlying disease or condition (other than the disease being studied), which may impact the ability of the participant to participate or potentially confound the study results.
- Has a coexisting disease affecting the esophagus (eg, esophageal varices, scleroderma, viral or fungal infection, or esophageal stricture), history of radiation therapy or cryotherapy to the esophagus, caustic or physiochemical trauma such as sclerotherapy to the esophagus.
- Has any findings in his/her medical history, physical examination, or safety clinical laboratory tests giving reasonable suspicion of underlying disease that might interfere with the conduct of the trial.
- Has a history of hypersensitivity or allergies to dexlansoprazole or any component of the formulation of dexlansoprazole capsules, or any proton pump inhibitor (PPI) (including lansoprazole, omeprazole, rabeprazole, pantoprazole, or esomeprazole) or antacids.
- Is required to take excluded medications or it is anticipated that the participant will require treatment with at least 1 of the disallowed concomitant medications during the study evaluation period.

... and 18 more (see full listing online)

Locations (33 total)

Childrens Center for Digestive Health Care, LLC, Mobile, Alabama, United States
University of Utah/ Primary Childrens Hospital, San Francisco, California, United States
Gastrointestinal Associates, PA, Centennial, Colorado, United States

... and 30 more locations