7803: A Preliminary Open-Label Trial of Losartan Potassium in Participants with Eosinophilic Esophagitis (EoE) With or Without a Connective Tissue Disorder

Status: RECRUITING

Study Summary

The Consortium of Eosinophilic Gastrointestinal Disease Researchers (CEGIR) is doing this study because the researchers want to learn more about eosinophilic esophagitis (EoE) when treated with losartan (a blood pressure medication). This study is sponsored and supported by the National Institute of Allergy and Infectious Diseases (NIAID), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), Office of Rare Diseases Research (ORDR), and the National Center for Advancing Translational Sciences (NCATS).

For Diseases

- Eosinophilic Esophagitis (EoE)

Background

People with a diagnosis of EoE, experience various symptoms in addition to visible and microscopic damage to their esophagus. There is no known cure for EoE, although effective treatments exist, such as swallowed steroid therapy and dietary restriction.

The purpose of this clinical study is to evaluate the impact of treatment of EoE with the drug losartan, which is a medication used in patients to control high blood pressure. Specifically, we will be see if losartan therapy reduces eosinophil number in the esophagus as well as improving EoE symptoms as measured by a questionnaire. Adults participating in the study may also choose to do EndoFlip to see if the esophagus becomes more flexible after treatment with losartan. EndoFLIP uses a special catheter that serves as a balloon and uses gentle pressure to see if the patient's esophagus is easy to inflate like a balloon or hard to inflate like a soccer ball.

About this Study

This is a pilot clinical drug trial of a small number of individuals with EoE, all of whom will receive losartan, a blood pressure medication used in adults and children, that was first approved by the FDA in 1995 for adult blood pressure control. In this study, we will instead use losartan's other effects to evaluate its impact on EoE. Participants will be seen at one of the clinical sites around the United States. After the first visit, participants will have several follow-up visits to monitor the impact of losartan on EoE.

For each visit, you will be asked to:

- Complete questionnaires that will take 30 to 45 minutes to complete

- Have blood drawn (at some visits)

As part of standard of care (your normal care) at each endoscopy you will:

- Have a biopsy (As part of standard of care endoscopy, the doctor will take small sections of your esophagus to check eosinophil counts, and the extent of injury related to EoE.)

Targeted Enrollment

To be eligible to participate, you must:

- Be male or female at least 5 years of age and no older than 25 years of age
- Be diagnosed with EoE:
  - However, you may **also** have mucosal eosinophilia at other sites **and/or** an eosinophilic gastrointestinal disease (EGID) like eosinophilic colitis (EC), eosinophilic gastritis (EG), etc.

You are not eligible to participate if:

- You have a history of esophageal surgery
- You are enrolled in a blinded investigational study
- You have esophageal stricture (<3mm)
- You have other identifiable causes for eosinophilia, infections, gastrointestinal (GI) cancer, other GI inflammatory disease

How to Join

In order to participate in a study, you must personally contact the study coordinator of any of the participating institutions by phone or by e-mail.

Ohio

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