Zemaira Eosinophilic Esophagitis Pilot Study

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 18 years to 70 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

1. Participant and/or legally authorized representative must be able to understand and provide informed consent prior to study procedures being performed.
2. Willing and able to comply with study visits and activities
3. Age ≥ 18 to ≤ 70 years at study enrollment
4. Histologically active eosinophilic esophagitis (EoE) at time of screening or within 12 weeks prior to enrollment, with a peak count of ≥ 15 eosinophils (eos)/high powered field (hpf) in any region of the esophagus, with no other known cause for esophageal eosinophilia; involvement of eosinophilic inflammation in other gastrointestinal segments will be allowed but not required or sufficient.
5. History of approximately 8 week standard of care (SOC) treatment (e.g., proton pump inhibitors (PPI's), topical corticosteroids) that did not adequately control or treat the EoE or documentation that such treatment was not tolerated. Participant may re-screen if this is not met.
6. Stable medical management of EoE (and other eosinophilic disorders, if applicable) including stable dosage of medications in the 8 weeks prior to study enrollment, if applicable. Participants may be on baseline anti-EoE therapy (such as elimination diet, elemental diet, proton pump inhibitors (PPI), topical or systemic glucocorticoids (≤10 milligrams (mg) daily), immunosuppressive agents, cromolyn, and H1 and H2 anti-histamines) as long as there is agreement not to change their dosage.
7. Willing to maintain current dietary regimen throughout the course of the study. Diet must have been stable for 8 weeks prior to baseline endoscopy.

Exclusion Criteria:

1. Inability or unwillingness of a participant to give written informed consent or comply with study protocol.
2. Current active H. pylori infection. A history of H. pylori infection needs to have medical documentation of one of the three acceptable eradication tests: antigen, breath or histology. Participants with current active H. pylori infections can be re-screened for study participation in the future if they are treated and have medical documentation of one of the three acceptable eradication tests: antigen, breath or histology.
3. Another disorder that causes esophageal eosinophilia (e.g., hypereosinophilic syndrome*, Churg Strauss vasculitis, eosinophilic granuloma or a parasitic infection).

*Hypereosinophilic syndrome defined by multiple organ involvement (with the exception of atopic disease or eosinophilic gastrointestinal disorder (EGID)) and persistent blood absolute eosinophil count ≥1500/microliter.
4. Systemic gastrointestinal disorders such as Crohn's disease, inflammatory bowel disease, or Celiac disease not including chronic gastritis, chronic duodenitis, mucosal eosinophilia or other EGID's.
5. Diagnosed with Chronic Obstructive Pulmonary Disease (COPD).
6. Known immunoglobulin A (IgA) deficiency (i.e., IgA level < 8 mg/dL at screening).
7. Current coronavirus disease of 2019 (COVID-19) infection (i.e., detection of the presence of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) before the screening endoscopy using testing done at the clinical site).
8. Hematological disorders that prevent the blood from clotting (e.g., hemophilia, Von Willebrand disease, clotting factor deficiencies).
9. Currently on anti-coagulation medications (except aspirin/Non-steroidal anti-inflammatory drugs).
10. Known history of hypersensitivity following infusions of human blood or blood components (e.g., human immunoglobulins or human albumin).
11. Known history of hypersensitivity or anaphylaxis to Zemaira or other A1AT products.
12. Uncontrolled, or poorly controlled, comorbid conditions including, but not limited to, cardiovascular diseases, hypertension and diabetes as defined by the following criteria:

* A myocardial infarction within the last 6 months.
* Blood pressure \> 179/99 mmHg
* Diabetics with a hemoglobin A1C (HbA1C) \> 7% and that are deemed to have uncontrolled diabetes as defined by the physician

1. History of cancer: Individuals who have had basal cell carcinoma, localized squamous cell carcinoma of the skin, or in situ carcinoma of the cervix are eligible provided that the participant is in remission and curative therapy was completed at least 12 months prior to the date informed consent was obtained. Individuals who have had other malignancies are eligible provided that the individual is in remission and curative therapy was completed at least 5 years prior to the date informed consent was obtained.
2. Current or recent use of any investigational drug (within 3 months or 5 half-lives, whichever is longer, prior to screening).
3. Currently participating or planning to participate in another clinical study involving an investigational drug during the course of this study.
4. Presence of steroid-responsive diseases (e.g., asthma) with a recent (within the last 6 months) history of disease exacerbations requiring steroid treatment.
5. Current use of systemic steroids with daily dose > 10 mg for any reason or steroid burst for > 3 days within 1 month of screening.
6. Current pregnancy or breastfeeding.
7. Any esophageal stricture unable to be passed with a standard, diagnostic upper endoscope.
8. Esophageal varices or interventional treatment for esophageal varices that, in the opinion of the investigator, would put the participant at undue risk for significant complications from an endoscopy procedure

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9. History of alcohol or drug abuse within 6 months prior to screening.
10. Participant or his/her immediate family is a member of the investigational team.
11. Presence of clinically significant laboratory abnormalities at the screening that meets one or more of the following criteria:

    1. Serum alanine aminotransferase (ALT) ≥ 3 times upper limit of normal (ULN)
    2. Serum total bilirubin ≥2 times ULN
    3. Absolute neutrophil count (ANC) ≤ 1000 cells/mm3
    4. Hemoglobin (Hgb) ≤ 10.0 g/dL
    5. Platelet count ≤ 100,000/mm3
    6. Glomerular Filtration Rate (GFR) ≤ 44 mL/min/1.73 m2
12. Planned or anticipated major surgical procedure during the study.
13. Known or suspected immunodeficiency disorder, including human immunodeficiency disorder (HIV) or a history of invasive opportunistic infections (e.g., tuberculosis, non-tuberculous mycobacterial infections, histoplasmosis, listeriosis, coccidioidomycosis, pneumocystosis, aspergillosis, or an infectious etiology of esophagitis (e.g. cytomegalovirus or Candida) despite infection resolution or otherwise recurrent infections of abnormal frequency or prolonged infections suggesting an immune-compromised status as judged by the investigator.
14. Planned or anticipated use of any prohibited medications and procedures during the study.
15. Currently on Zemaira for other indications.
16. Initiation, discontinuation or change in the dosage regimen of the following medications within 8 weeks prior to the baseline endoscopy:

    Proton pump inhibitors Leukotriene inhibitors Nasal and/or inhaled corticosteroids Participants on a stable dose of these medications for at least 8 weeks prior to the baseline endoscopy may be included in the study. PPI and leukotriene inhibitor dosing must not change during the study, but nasal and/or inhaled corticosteroids can be increased if there is a deterioration in the condition for which the medications are prescribed.
17. Presence of the following esophageal disorders: achalasia cardia, Barrett's esophagus or precancerous lesions noted on the endoscopy.
18. Women of childbearing potential, or male participants with female partners of childbearing potential, who are unwilling to practice highly effective contraception prior to the initial dose/start of the first treatment, during the study, and for at least 12 weeks after the last dose. Highly effective contraceptive measures include:

    1. Stable use of combined (estrogen and progestogen containing) hormonal contraception (oral, intravaginal, transdermal) or progestogen-only hormonal contraception (oral, injectable, implantable) for one month prior to screening
    2. Intrauterine device; intrauterine hormone-releasing system
    3. Bilateral tubal ligation
    4. Vasectomized partner
    5. And/or sexual abstinence
19. Past or current medical problems or findings from physical examination or laboratory testing that are not listed above, which, in the opinion of the investigator, may pose additional risks from participation in the study, may interfere with the participant's ability to comply with study requirements or that may impact the quality or interpretation of the data obtained from the study.

Conditions & Interventions

Interventions:
DRUG: Alpha-proteinase inhibitor
Conditions:
Eosinophilic Esophagitis

More Information

Description:
This is a prospective, open-label drug study that will examine the effects of Zemaira (alpha-1 trypsin inhibitor) in patients with Eosinophilic Esophagitis.

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Principal Investigator ID:
Phase: PHASE2
IRB Number:
System ID: NCT05485155

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