



About Research Studies

Pharmaceutical companies use research studies like the Liberty EoE TREET study to learn more about the safety and effectiveness of investigational drugs. The information collected in this study will help doctors and researchers determine if the investigational drug could one day become available to the public. By participating in the Liberty EoE TREET study, you will be contributing to eosinophilic esophagitis (EoE) treatment research.

To learn more about the Liberty EoE TREET study, please contact:

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Is

EoE

getting in the
way of your diet
choices?

Learn more about the Liberty EoE TREET study of an investigational drug for patients diagnosed with **eosinophilic esophagitis (EoE)** and who are experiencing dysphagia.

As an eosinophilic esophagitis (EoE) patient or the parent of an eosinophilic esophagitis (EoE) patient, you know all too well how painful and frustrating this medical condition is.

It changes your food choices and forces you to make decisions about which treatment or medical procedure might be best for you or your child.

While eosinophilic esophagitis (EoE) treatments are available, options are limited. Currently used options can disrupt quality of life, have limited efficacy, or only address the symptoms and not the cause of the disease. As a result, research into additional eosinophilic esophagitis (EoE) treatment options is needed.

To help potentially meet this need, local doctors are conducting the Liberty EoE TREET study to evaluate an investigational drug for the treatment of eosinophilic esophagitis (EoE). They want to learn more about the investigational drug's effect on relieving eosinophilic esophagitis (EoE) symptoms and reducing inflammation in the esophagus.

Doctors want to compare the investigational drug to placebo, which looks like the investigational drug but contains no active medication. The investigational drug and placebo are both given through subcutaneous injections (needle inserted under the skin).

The results of this study will provide more information about the investigational drug and whether it could one day be used to treat eosinophilic esophagitis (EoE) symptoms.

What is the investigational drug?

The investigational drug being evaluated in this study is called dupilumab. It is a type of protein that the body normally makes to fight bacteria and viruses. In previous research studies, dupilumab showed the ability to block the action of other proteins that may be involved in inflammatory diseases like eosinophilic esophagitis (EoE).

Dupilumab has been approved for the treatment of asthma and moderate to severe eczema, but it has not been approved to treat eosinophilic esophagitis (EoE). As a result, it is considered investigational for the purposes of this study.

Who is eligible to participate in the Liberty EoE TREET study?

To pre-qualify for this study, you must:

- Be 12 years of age or older
- Have a medical diagnosis of eosinophilic esophagitis (EoE)
- Have had at least two episodes of difficulty swallowing per week in the month prior to beginning this study

All study-related visits, tests, and drugs will be provided to you. In addition, you will be reimbursed for study-related travel.

What will happen during the Liberty EoE TREET study?

If you are eligible for this study and agree to participate, you will be randomly assigned (like flipping a coin) to receive either the investigational drug or placebo. Based on when you join the study, you have either a one out of two or two out of three chance of receiving the investigational drug.

You, the study doctor, and the study staff will not know whether you are receiving the investigational drug or placebo. This is to prevent any opinions from affecting the study results. However, in the event of an emergency, that information can be provided.

During the first part of this study, you will receive one injection a week for 24 weeks. If you complete the first part of the study, you may have the opportunity to continue into the second part of the study. In the second part of the study, all patients will receive injections of the investigational drug for 28 weeks.

Your total study participation may last up to 18 months, which includes approximately 20 visits to the study clinic for tests and assessments.

What are the benefits and risks related to the Liberty EoE TREET study?

You may not personally benefit from participating in this study. However, your participation may provide new information about the effects of the investigational drug in people with eosinophilic esophagitis (EoE).

It is possible you could experience a side effect while in this study. Before you begin the study, a member of the study staff will discuss the potential side effects and risks with you.

Because this study could affect your health, you will be closely monitored. The sponsor of this study designed a protocol, which explains all study procedures. An independent review board responsible for participant safety reviewed this protocol and requires that it is followed exactly.

Comprehensive information about this study, including risk information, is provided in the Informed Consent Form.