

## What is a clinical study?


A clinical study (such as LIDS) involves research that is intended to add to medical knowledge related to the treatment of diseases or conditions (such as TED). Clinical studies enroll volunteers (also called participants) to help researchers compare an investigational drug to a placebo that contains no active ingredients.

## What is an investigational drug?

An investigational (or study) drug is a drug that is being tested in clinical studies. Linsitinib is the investigational drug in the LIDS study. Investigational drugs may or may not be approved by the government health agency. However, every investigational drug must be reviewed, approved, and monitored by an ethics committee for testing in clinical study participants.

## Why should I take part in the LIDS study?

A clinical study provides the basis for the development of new drugs. The results of these studies can make a difference in the care of future patients by providing information about the benefits and risks of therapeutic drugs. Current treatments for diseases like TED are only available because of research study volunteers like you.



Thank you for your  
interest in the LIDS study  
for adult thyroid eye disease.

For more information, please visit  
**LIDSStudy.com** or contact:

Caroline Beard / (832) 643-7715 / [cbeard@lfros.com](mailto:cbeard@lfros.com)

or

Laura Perez / (281) 723-8593 / [lperez@neuroeye.com](mailto:lperez@neuroeye.com)

[www.lfrosresearch.com](http://www.lfrosresearch.com)



Your journey with  
thyroid eye disease (TED)  
is grounded in hope.  
So is clinical research.

Ask your doctor if you are eligible for the LIDS study.



VGN-TED-301\_patient\_brochure\_v1.1\_24May2022\_English



## What is the LIDS study?

Thyroid eye disease (TED) is a condition where the immune system attacks the muscle and tissue around the eyes. Typically the active or inflammatory stage of TED lasts one to three years and symptoms can range from mild to severe. Symptoms of TED may include bulging eyes, redness, irritation, swelling, and double or blurry vision. If left untreated, these symptoms may potentially lead to severe vision problems or even vision loss.

Researchers continue to explore TED and possible study drugs for these patients through clinical studies like LIDS. The LIDS study is testing an investigational (or study) drug to see how it works in adults with active, moderate-to-severe TED. Study volunteers can help us in this important research. Thank you for considering participation in this study.

## What is the purpose of this study?

This study is investigating a study drug called linsitinib to find out how well it works compared to placebo in adults with active, moderate-to-severe TED. A study drug (or investigational drug) is one that is being tested in clinical research studies and not approved for use by the general public. Placebo is a drug that looks like the study drug but has no active ingredients in it.

## Who can participate in the LIDS study?

### To be eligible for this study, you must:

- **Be at least 18 years of age or older**
- **Have active, moderate-to-severe TED (current symptoms that significantly impact your quality of life) that started within the past year**
- **Be diagnosed with Graves' disease and/or Hashimoto's disease associated with TED**

This is not a complete list of study requirements. The study doctor will review the full requirements for this study with you.

## How long will this study last?

Participants will be in this study for approximately 124 weeks (a little over 2 years).

## What risks are involved if I decide to participate?

There are possible risks involved with any clinical study. The study doctor will review the risks with participants, and participants will be closely monitored throughout the study.

## What can I expect if I decide to participate?

After your eligibility is determined during the screening period, you will be assigned to a study drug or placebo group at the beginning of the study treatment period. During this period, you will take either the study drug linsitinib or placebo tablets by mouth twice daily. Your group assignment is done randomly (by chance; like drawing straws) by a computer. Your study group assignment is double-masked, which means you and your study doctor will not know which study group you are in or what study drug or placebo you are taking.

After you complete the study treatment period, you will stop taking linsitinib or placebo. You will either enter a 48-week follow-up period or if you qualify, you may choose to enroll in an extension study where all participants will receive linsitinib. The study staff will talk to you about whether you will begin the follow-up period or if you are eligible to enter the extension study.

Laboratory tests, physical and eye exams, and other assessments and questionnaires will be conducted as part of this study.

## What are my costs to take part in the LIDS study?

You do not have to pay for the study drug, placebo, study supplies, or tests that are part of the LIDS study.

