

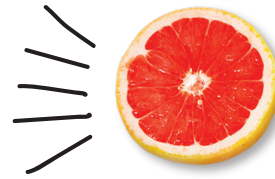
ABOUT CLINICAL RESEARCH STUDIES

Clinical research studies are designed to answer specific questions about investigational drugs and are needed to help find new and possibly better future treatments for diseases.

An investigational drug goes through several phases of clinical research to evaluate its safety and effectiveness. Depending on the results of the research, the drug could later be available to the public.

Clinical research studies are performed in accordance with strict governmental guidelines. These guidelines help ensure that the study participants' safety and rights are protected during the clinical research study, while allowing valuable information about the investigational drug to be collected.

Volunteering to participate in a clinical research study is an important decision that should be thought through carefully. Participation is entirely voluntary and an individual has the right to decline participation or to discontinue at any time, for any reason, and without penalty or loss of any of the benefits to which they would otherwise have been entitled.



WANT TO KNOW MORE?

If you would like more information about this clinical research study, please contact the number below. Contacting us does not mean that you will then be obliged to participate, nor is it certain that you will be suitable to participate.

Thank you. We hope to hear from you soon.



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Are you
experiencing

CELIAC DISEASE SYMPTOMS

even on a *gluten-free diet*?

www.celiac-study.com

4051 0004 Study Brochure v1.0 US (English) 19June19

The CeD-LA-3001 Study
for celiac disease.

WHY IS THE RESEARCH STUDY BEING CONDUCTED?

There is no cure for celiac disease. Currently, the only effective treatment to manage celiac disease symptoms is to maintain a gluten-free diet, but not every patient responds, and symptoms can still occur. Gluten can be hidden in unexpected places like medications or food labeled gluten-free, and celiac disease symptoms can even occur from very small amounts of gluten.

CeD-LA-3001 STUDY



The **CeD-LA-3001 Study** is being done to determine if the investigational drug reduces symptoms

of celiac disease in adults who are on a gluten-free diet and if the study drug changes the inflammation in the intestine.

Approximately 630 people will participate in this research study at approximately 200 clinical centers in North America. Participation in the study will last about 29 weeks during which there will be about 8 visits to the study center.

The study will compare the investigational drug to a placebo. A placebo is a capsule that looks like the investigational drug but contains no active ingredients.

WHO CAN TAKE PART IN THIS STUDY?



This study is for adults 18 years of age who have been diagnosed with celiac disease.

You may qualify if you:

- ✓ Are 18 years of age or older
- ✓ Were diagnosed with celiac disease 6 or more months ago
- ✓ Are actively experiencing symptoms related to celiac disease
- ✓ Have been on a gluten-free diet for at least 6 months

There are also other study requirements that will determine if you qualify. With your permission, these criteria will be reviewed by the study doctors and nurses when you contact or visit the research center listed on the back of this leaflet.

WHAT WILL STUDY PARTICIPANTS BE ASKED TO DO?

If you choose to participate and the study doctor determines you are eligible, you will be asked to attend approximately 8 office visits over a 29 week period.

The first step will be to meet with a member of the study team at your local research center to review an Informed Consent Form. This form fully explains the purpose of the study, possible risks and benefits, and what will be expected of you as a participant. No procedures will begin until you have had all your questions answered and have signed this form, signifying your understanding of its contents and your agreement to take part.

Study participants will be randomly (by chance) assigned to one of three groups. Participants in group 1 and 2 will take the investigational drug, and those in group 3 will take a matching placebo. During the study, participants will be asked to maintain a gluten-free diet.

During this time, all study visits and the study drug will be provided to the patient at no charge.

You may withdraw from the research study at any time by telling the study doctor or study staff.

