

SOFEEED Study for Patients with Eosinophilic Esophagitis (EoE)

What is the purpose of this study?

The purpose of this research study is to test the effects of two elimination dietary therapies—the 1 Food Elimination Diet (1FED) (Milk) vs. the 6 Food Elimination Diet (6FED) (Milk, Egg, Wheat, Soy, Peanut/tree nuts, and fish/shellfish) in patients diagnosed with EoE. This study also aims to test participant's response to swallowed glucocorticoids (Flovent) in participants who do not respond to the 6-Food elimination diet. Flovent is a topical steroid (taken using an inhaler) approved by the FDA to treat asthma, but that is also used for patients with EoE.

Who can participate?

Adults ages 18-60 years that have been diagnosed with EoE.

What is involved?

Each individual who qualifies and agrees to participate will be randomly assigned to one of the two dietary therapies (1FED or 6FED). You will receive study-related medical examinations, the analysis of research biopsies, and laboratory tests at no charge. Participants who do not respond to the 6FED dietary therapy (in Phase 1) will receive study drug at no charge. Your medical information will also be collected. You will be asked to complete diaries and questionnaires about your symptoms, diet, and quality of life. Your name will never be published.

What are the benefits?

It is possible that you will receive little or no benefit from the dietary therapies and/or study drug in this study. We do think that the information from this study will help researchers learn more about the dietary therapies and study drug as potential treatments for EoE. The information gained in this study may be useful in helping people with EoE in the future.

Will I get all the facts about the study?

If you are interested in participating in this study, you will meet with a study coordinator who will explain all of the details of the study. The study coordinator will review the consent form and will be sure that all questions are answered. The consent form describes all the procedures, risks and benefits and whom to contact with questions or concerns. Study procedures will not begin until the consent has been signed by the participant.

Who should I contact for more information?

Jonathan Kuhl, BS
513-803-3078
Jonathan.kuhl@cchmc.org
The Cincinnati Center for Eosinophilic Disorders
Cincinnati Children's

SOFEEED Web Text
Version 1: March 26, 2015

3333 Burnet Avenue, MLC 2010
Cincinnati, OH 45229-3026

Principal Investigator:

Marc E. Rothenberg, M.D., Ph.D.

Where can I find additional information?

<https://www.rarediseasesnetwork.org/cms/CEGIR>