

Do You or a Loved One Have a Peanut Allergy?

Needed: 6 to 55 Year Olds for Peanut Allergy Medication Research Study

What is the purpose of this study?

This is a research study to evaluate the safety and effectiveness of the investigational medication Viaskin® Peanut for treating peanut allergy in children and adults.

Why is this study being done?

To date, there is no specific approved treatment for peanut allergy, which can be quite severe and life-threatening. The only management recommended for patients allergic to peanuts is strict avoidance. However, peanut is a very common ingredient in many foods and is not always reported in all ingredients.

Who can participate?

Children and adults 6 to 55 years old who have a well-documented history of peanut allergy and are currently following a strict peanut-free diet may be eligible to participate.

What is involved?

If you choose to participate, you will be in the research study for 58 weeks, or a little over a year, and be asked to complete 12 study visits.

During the study visits at the clinic, you will receive the study medication or a placebo, a substance that looks like the study medication but has no active ingredient in it, via a patch on your skin, as well as complete health-assessments, including:

- Health, medication and demographic questions
- Physical exams
- Vital sign measurements
- Allergy skin prick test
- Lung function tests
- Food challenge
- Blood and urine tests

You will be given a diary to take home and complete on a daily basis. You will need to bring the diary with you to each study visit.

A detailed list of procedures will be provided to anyone interested in knowing more about this study.

What are the benefits?

You may or may not receive a direct medical benefit from being in this study. However, the information gained from this study may help researchers understand more about peanut allergy and develop new tests or medications to help others in the future.

Will I get all the facts about the study?

You will be given a consent form that thoroughly explains all of the details of the study. The form covers all of the procedures, the risks, the benefits, the pay, who to contact with questions or concerns and more. A member of the study staff will review the consent form with you and will be sure that all of your questions are answered.

What are the risks and discomforts of this study?

All drugs carry a risk of side effects. Everyone taking part in the study will be observed by the study doctor and staff for any side effects.

Other possible discomforts or risks will be discussed with you if you are interested in learning more about the study.

Do participants receive pay, compensation or reimbursement?

Participants may receive up to \$480 for travel related expenses for completing all 12 study visits (\$40 per completed study visit).

Who should I contact for more information?

Lisa Thornbury
513-803-FOOD (3663)
foodstudies@cchmc.org
Cincinnati Children's Hospital Medical Center
Division of Allergy and Immunology
3333 Burnet Avenue
Cincinnati, OH 45229-3039

Principal Investigator:

Amal Assa'ad, MD
Division of Allergy and Immunology
Cincinnati Children's Hospital Medical Center