Adults 18 to 55 with Non-Severe Peanut Allergy Needed for a Research Study

Why is Cincinnati Children's doing this research?
We want to learn more about the safety and tolerability of an investigational peanut vaccine study drug for adults with non-severe peanut allergies.

We want to see if the peanut vaccine study drug will train the immune system not to have an allergic reaction when the body comes in contact with peanut proteins.

Who can participate?
Adults, 18 to 55 years old, with a well-documented history of a non-severe allergy to peanuts or peanut–containing foods, may be eligible to participate.

Will I get the facts about the study?
You will be given a consent form that thoroughly explains all of the details of the study. A member of the study staff will review the consent form with you and will be sure that all of your questions are answered.

How long is this study? How many visits?
If you qualify for this study and you agree to participate, you will come to Cincinnati Children's for up to 13 study visits over the next 8 ½ months.

What will happen during this research study?
While you are in this research study, study staff will collect information from you and ask you to perform the following tests and procedures during 1 or more study visits:

- Demographic (personal) information
- Medical and medication history
- Vital sign measurements: height, weight, temperature, blood pressure and pulse
- Physical exam
- Spirometry: a lung function test
- Blood samples: for routine lab and safety tests
- Urine samples: for routine lab, safety and pregancy tests (if you are female)
- Skin prick test (SPT): a small amount of an allergen is placed under the surface of the skin (via a prick or scratch) and watched for an allergic reaction
- Double-blinded placebo-controlled food challenge (DBPCFC): 2 food challenges (1 with peanut and 1 without) during which you will eat increasing amounts of food every 30 minutes (neither you nor your doctor will know if you are eating peanut or placebo)
- Electrocardiogram (ECG): measures the function of the heart
- Diary: for recording symptoms following a study drug dosing

You will first take part in 2 separate screening periods (up to 35 days before the study drug dosing) to determine if you can participate in the rest of this study. The tests and procedures during the screenings, including a skin prick test and food challenge, will each take up to 6 hours to complete.

If you are eligible to continue after the screenings, you will return to Cincinnati Children's for your first study drug dosing visit. During this visit, you will be randomly assigned (by chance, like flipping a coin) into 1 of 3 different groups to receive either the active study drug or placebo. A placebo looks like the study drug but contains no active ingredient. Neither you nor study staff will know if you are receiving the active study drug or placebo but can find out in an emergency.

After randomization, depending on your assigned group, you will receive your first dose of study drug via intradermal (into the skin) injection or intramuscular (into a muscle) injection. You will need to stay at the clinic for about 2 hours after you receive the study drug until all tests, procedures and observations are completed. If you do not show any signs of any allergic symptoms or reactions, you will be able to go home. If the doctor feels you are showing signs, you will be asked to stay for additional observation.

You will return for 3 more study drug dosing visits, each 2 weeks apart and lasting about 3 to 4 hours (including dosing, observation, tests and procedures).

After each of your study drug dosing visits, you will be asked to record any allergic symptoms or reactions in a diary for 7 days. We will also contact you by phone 24 hours after each dose to see how you are feeling.

When your dosing visits are complete, you will be followed for an additional 6 months and have 4 follow-up visits and 1 study completion visit. The tests and procedures completed at these visits, which will each last about 3 hours, are to monitor your continued safety (you will not receive any more study drug).

What are the good things that can happen from this research?
You may or may not receive any direct medical benefit from being in this study. Your condition may improve, worsen or stay the same. However, the information we learn from this study may be helpful to others who need the same treatment in the future.

What are the bad things that can happen from this research?
Possible risks and side effects will be discussed with you if you are interested in learning more about the study.

Will I be paid to be in this research study?
Participants will receive up to $1300 ($200 per visit with a food challenge and $100 for all other visits) for their time and travel.

Who should I contact for more information?
Xxxxx Xxxxxx
xxxx.xxxxx@cchmc.org
XXX-XXX-XXXX

Study Doctor:
Amal Assa'ad, MD
Associate Director, Division of Allergy and Immunology
Director of Clinical Services, Division of Allergy and Immunology

Cincinnati Children's™
Research Foundation

cincinnatichildrens.org/clinical-studies
facebook.com/cincinnatichildrensstudies
pinterest.com/cincykidstrials

CCHMC IRB #2016-6454X: V1 BRV162713