

Who will qualify for this clinical trial?

Are you:

Between 12-24 years old?

Do you have an allergy to any of these foods?

peanut • tree nuts • sesame • fish • shellfish

What is involved in participation:

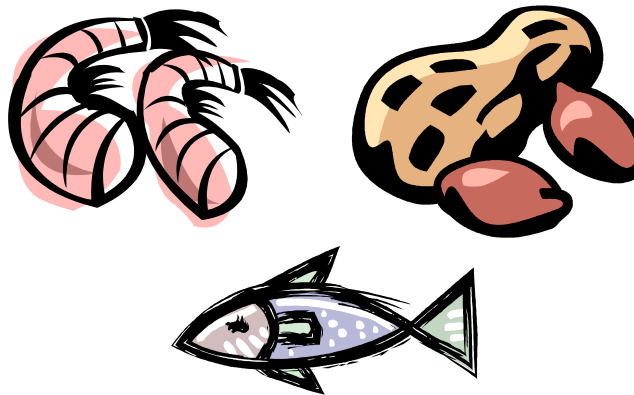
- Skin prick testing
- Blood draw
- Oral food challenge
- Taking the Chinese herb mixture pill
- The study is approximately 9 months long

This clinical trial is supported by the National Center for Complementary and Alternative Medicine (NCCAM), National Institutes of Health (NIH) and Food Allergy Initiative.

www.clinicaltrials.gov

Search "Chinese herbs food allergy"

Children's Memorial Hospital
Department of Pediatrics
Division of Allergy & Immunology
2300 Children's Place, Box 60
Chicago, IL 60614



This study is CMH IRB #2011-14582, Dr. Jacqueline Pongracic, Principal Investigator. The content of this letter/notice has been approved by the CMH IRB.

Food Allergy Research



Traditional Chinese Medicine
for the treatment of
Food Allergies

Are you between 12-24 years old?

Are you allergic to peanuts, tree nuts, sesame, fish, or shellfish?

Children's Memorial Hospital in Chicago is currently enrolling volunteers for a new clinical study that will determine the effectiveness of Chinese herbs for the treatment of food allergy.

All study-related visits and laboratory test are provided at no cost.

**For more information, please contact
1.888.573.1833 (toll free) OR
allergystudy@childrensmemorial.org**

Chinese Herbal Medicine Food Allergy Clinical Trial – Children’s Memorial Hospital

TRADITIONAL CHINESE MEDICINE FOR TREATMENT OF FOOD ALLERGY

FOOD ALLERGY



- Food allergy affects as many as 6% of young children and 3%-4% of adults.
- Peanut allergy is the leading cause of food-induced anaphylaxis treated in hospital emergency departments in the U.S.
- The prevalence of childhood peanut allergy doubled between 1997 and 2002, and unlike other food allergies, peanut and tree nut allergies are rarely outgrown.
- Seafood allergy, which includes finned fish, shrimp, crab, lobster, clams, squid, scallop, and snails affects an estimated 2.3% of Americans.
- At the present time, there is no effective therapy for food allergies other than immediate access to rescue medications, and strict avoidance is the only way to manage this condition.

What is

Traditional Chinese Medicine?

Traditional Chinese Medicine (TCM) has been used in China to treat various diseases for thousands of years. TCM uses formulas composed of Chinese herbs that work together to produce results and have reduced side effects.

Mount Sinai medical researchers developed the nine-herb formula, FAHF-2, used in this study for the treatment of food allergy.

In China, TCM is used alone or alongside western therapies. It is useful as an alternative or complementary therapy because of its effectiveness, low cost, and limited side effects.

FAHF-2 USE AND SAFETY

When used according to traditional Chinese herbology, the herbs in the study drug Food Allergy Herbal Formula 2 (FAHF-2) have been utilized over long periods of time for hundreds of years without known ill effects.

A 6-month safety study for FAHF-2 was completed in people with a variety of food allergies. Mild gastrointestinal complaints occurred and did not need treatment.

PURPOSE OF THE STUDY

This Phase II study of the drug Food Allergy Herbal Formula 2 will test its effectiveness in treating food allergy and further determine any safety risks.

BENEFITS OF THE STUDY

- Advancement of food allergy clinical research, which is necessary because there is not yet a treatment for food allergy.
- Development of the first active therapeutic treatment for food allergy if FAHF-2 proves to be safe and effective.
- Participants receive accurate diagnosis of food allergy to peanut, tree nut, fish, shellfish, or sesame.
- Treatment with FAHF-2 may result in general improvement of allergic symptoms for participants.
- Potential contribution to the future health of others with food allergies.