

Induction of tolerance through early introduction of peanut in high-risk children

Submission date
19/12/2006

Recruitment status
No longer recruiting

Prospectively registered

Protocol

Registration date
04/04/2007

Overall study status
Completed

Statistical analysis plan

Results

Last Edited
29/01/2016

Condition category
Injury, Occupational Diseases, Poisoning

Individual participant data

Plain English summary of protocol

Background and study aims

The number of children in the Western World that have a peanut allergy has doubled in the past ten years and the allergy is now also found in Africa and Asia. It is the leading cause of food allergy related anaphylaxis (acute allergic reaction) and death. The allergy develops early in life and is generally life-long. Studies have suggested that the earlier peanuts are introduced to a child's diet, the less likely they are to develop an allergy to them. This study looks at whether giving children that are considered at higher risk of developing a peanut allergy (as they are already allergic to eggs or have severe eczema) earlier in life reduces the risk of them actually becoming allergic to peanuts.

Who can participate?

Children aged between 4 months and 11 months that have an egg allergy, severe eczema, or both.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group are fed a peanut-containing snack-food at least three times each week until they are 5 years old. Those in the second group avoid eating food containing peanuts until they are 5 years old. All the children are followed up to see which ones develop a peanut allergy.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

Evelina Children's Hospital, London (UK)

When is the study starting and how long is it expected to run for?

November 2006 to July 2013

Who is funding the study?

1. US National Institute of Allergy & Infectious Diseases
2. Immune Tolerance Network (USA)

3. Food Allergy Initiative (USA)
4. Food Standards Agency (UK)

Who is the main contact?
Professor Gideon Lack
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00329784

Protocol serial number
ITN032AD Lack

Study information

Scientific Title
Induction of tolerance through early introduction of peanut in high-risk children

Acronym
LEAP (Learning Early About Peanut allergies)

Study objectives
This study will evaluate whether early avoidance or exposure to peanuts promotes tolerance and provides protection from developing peanut allergy in children who are at high risk as determined by allergy to eggs or severe eczema.

Ethics approval required
Old ethics approval format

Ethics approval(s)

St. Marys Research Ethics Committee, 23/10/2006, ref: 04/Q0413/13

Study design

Randomised controlled single-site trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Peanut allergy, peanut hypersensitivity, eczema, egg hypersensitivity, food hypersensitivity

Interventions

Participants assigned to the peanut consumption group will be fed at least 6 g of peanut protein per week, distributed over at least three meals per week during study participation. The preferred peanut source will be Bamba, however, peanut butter may be substituted. Participants assigned to the peanut avoidance group will avoid exposure to peanut protein during study participation.

Intervention Type

Supplement

Primary outcome(s)

The proportion of participants with peanut allergy at 60 months of age.

Key secondary outcome(s)

1. Effect of peanut consumption on other allergy outcomes
2. Safety of peanut consumption among study participants
3. Immunologic mechanisms by which consumption of peanut may induce tolerance to peanuts

Completion date

01/07/2013

Eligibility**Key inclusion criteria**

1. Children greater than four months and less than 11 months of age
2. Have had solid foods introduced successfully into their diet
3. Egg allergy, severe eczema or both

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

4 months

Upper age limit

11 months

Sex

All

Key exclusion criteria

1. Clinically significant chronic illness, except for eczema or recurrent wheeze
2. Positive skin prick test for peanut allergen with a wheal diameter of greater than 4 mm
3. Previous or current consumption of peanut
4. Previous allergic reaction to peanut
5. Sibling or other household member who is allergic to peanut
6. Certain other immunological criteria

Date of first enrolment

29/11/2006

Date of final enrolment

01/07/2013

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Evelina Children's Hospital

London

United Kingdom

SE1 7EH

Sponsor information

Organisation

Immune Tolerance Network for National Institute of Allergy and Infectious Diseases

ROR

<https://ror.org/043z4tv69>

Funder(s)

Funder type

Government

Funder Name

US National Institute of Allergy & Infectious Diseases

Funder Name

Immune Tolerance Network (USA)

Funder Name

Food Allergy Initiative

Alternative Name(s)

FAI

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United States of America

Funder Name

Food Standards Agency

Alternative Name(s)

The Food Standards Agency, FSA

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	26/02/2015		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes