ISRCTN94818122 https://doi.org/10.1186/ISRCTN94818122

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

Submission date	Recruitment status	[_] Prospectively registered
19/12/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/04/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/01/2016	Injury, Occupational Diseases, Poisoning	

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 course 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 childs 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
info@leapstudy.co.uk

Study website
http://www.leapstudy.co.uk

Contact information

Type(s)
Scientific

Contact name
Prof Gideon Lack

Contact details
Evelina Children's Hospital
Guy's & St. Thomas' NHS Foundation Trust
Lambeth Palace Road
London
United Kingdom
SE1 7EH
+44 (0)20 7188 9784
info@leapstudy.co.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00329784

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Patient information can be found at: http://www.leapstudy.co.uk/participating.html

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

Secondary outcome measures
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

Overall study start date

29/11/2006

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

Age group
Child

Lower age limit
4 Months

Upper age limit
11 Months

Sex
Both

Target number of participants
480

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
England

United Kingdom

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

Sponsor details
185 Berry Street
Suite 3515
San Francisco
United States of America
94107
+1 415 353 4418
nnasser@immunetolerance.org

Sponsor type
Government

Website
http://www.immunetolerance.org

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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