

Study of Tolerance to Oral Peanut

Submission date 29/04/2010	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 29/04/2010	Overall study status Completed	☐ Protocol
Last Edited 03/02/2015	Condition category Injury, Occupational Diseases, Poisoning	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

7993; EME 08/99/18

Study information

Scientific Title

Study of Tolerance to Oral Peanut: a randomised controlled trial of oral peanut immunotherapy

Acronym

STOP

Study objectives

The hypothesis is that peanut oral immunotherapy will result in an increase in tolerance to peanut in peanut-allergic children.

Link to EME project website: <http://www.eme.ac.uk/projectfiles/089918info.pdf>

Ethics approval required

Old ethics approval format

Ethics approval(s)

MREC approved on the 01/02/2010 (ref: 09/H0308/154)

Primary study design

Interventional

Study design

Randomised interventional treatment trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Generic Health Relevance and Cross Cutting Themes; Subtopic: Generic Health Relevance (all Subtopics); Disease: Paediatrics

Interventions

There are two work packages:

Package 1:

The active group will undergo oral peanut immunotherapy (OIT - the intervention) and the control group will undergo a waiting list period of current standard management for 5 months. Both groups will then undergo double blind peanut challenge to determine tolerance.

Package 2:

Those subjects in the waiting list control group who are still allergic at the end of the period of standard management will undergo peanut immunotherapy. After active treatment the control group will undergo a final double blind peanut challenge. Peanut oral immunotherapy consists of daily doses of oral peanut flour. The dose increases every 2 weeks according to the schedule: 5, 12, 25, 50, 100, 200, 400, 800 mg peanut protein equivalence.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Proportion of subjects in the active and control groups who pass a peanut challenge

Key secondary outcome(s)

1. Adverse effect of immunotherapy, laboratory assays

Completion date

31/08/2013

Eligibility

Key inclusion criteria

1. Aged greater than 7 years, either sex
2. Peanut allergy defined as a clear history of a typical immediate reaction following definite peanut ingestion

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Other

Sex

Not Specified

Key exclusion criteria

Major immunodeficiency (this will influence outcome)

Date of first enrolment

01/09/2009

Date of final enrolment

31/08/2013

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Addenbrookes Hospital

Cambridge

United Kingdom

CB2 2QQ

Sponsor information

Organisation

Addenbrooke's Hospital (UK)

ROR

<https://ror.org/055vbx86>

Funder(s)

Funder type

Government

Funder Name

Medical Research Council (MRC)/National Institutes of Health Research (NIHR) (UK) - Efficacy and Mechanism Evaluation (EME) Programme (ref: EME 08/99/18)

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	12/04/2014		Yes	No
Results article	results	01/12/2014		Yes	No