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Study of Tolerance to Oral Peanut

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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)

Study design
Randomised interventional treatment trial

Primary study design
Interventional

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 immunotherpy 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/055vbxf86

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