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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

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
1. Adverse effect of immunotherapy, laboratory assays

Overall study start date
01/09/2009

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

Age group
Other

Sex
Not Specified

Target number of participants
Planned Sample Size: 104; UK Sample Size: 104

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
England

United Kingdom

Study participating centre
Addenbrookes Hospital
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Addenbrooke's Hospital (UK)

Sponsor details
Addenbrookes Hospital
Hills Road
Cambridge
England
United Kingdom
CB2 2QQ

Sponsor type
Hospital/treatment centre

Website
http://www.cuh.org.uk/addenbrookes/addenbrookes_index.html

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

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