ISRCTN11376766 https://doi.org/10.1186/ISRCTN11376766

Determination of intranasal allergen threshold to egg in children with egg allergy

Submission date	Recruitment status
16/01/2014	No longer recruiting
Registration date	**Overall study status**
16/01/2014	Completed
Last Edited	**Condition category**
11/05/2017	Injury, Occupational Diseases, Poisoning

- [ ] Prospectively registered
- [ ] Protocol
- [ ] Statistical analysis plan
- [ ] Results
- [ ] Individual participant data
- [ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
15942

Study information

Scientific Title
Determination of intranasal allergen threshold to egg in children with egg allergy

Acronym
INATE Study

Study objectives
Determination of intranasal allergen threshold to egg in children with egg allergy

Ethics approval required
Old ethics approval format

Ethics approval(s)
14/WM/0016

Study design
Non-randomised; Interventional; Design type: Diagnosis, Not specified, Prevention

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Topic: Medicines for Children Research Network; Subtopic: All Diagnoses; Disease: All Diseases

Interventions
Primary Intervention, Sequential, incremental doses of aerosolised (food grade) egg white (egg protein) at 0, 0.1,
1, 10 and (where no symptoms are present) 100 µg per nostril (in sterile normal saline), at
30 minute intervals, using a nasal spray.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Immediate allergic reaction (<30mins following administration)

Secondary outcome measures
Not provided at time of registration

Overall study start date
06/01/2014

Completion date
03/10/2014

Eligibility

Key inclusion criteria
1. Aged 6 - 17 years old

2. Physiciandiagnosis of egg allergy on the basis of: Positive oral food challenge to egg (conducted under medical supervision) within the last 12 months OR History of convincing clinical reaction to egg within the last 12 months AND positive skin prick test within last 6 months OR Evidence of >95% likelihood of egg allergy (on the basis of serum specific IgE 6.0 IU /mL or above or skin prick test (SPT) 6mm or above to egg white within past 12 months but with no history of oral tolerance to egg
3. Written informed consent from parent/guardian, with assent from children aged 8 years and above wherever possible.

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Years

Upper age limit
17 Years

Sex
Both

Target number of participants
Planned Sample Size: 12; UK Sample Size: 12

Key exclusion criteria
1. Contraindicated as acutely unwell or current unstable asthma
1.1. Acute wheeze in last 72 hours requiring treatment
1.2. Febrile =380 deg C in last 72 hours
1.3. Recent admission to hospital in last 2 weeks for acute asthma
2. Current medication
2.1. Use of asthma reliever medication in last 72 hours

2.2. Recent administration of a medication containing antihistamine within the last 4 days
2.3. Current oral steroid for asthma exacerbation or course completed within last 2 weeks

Date of first enrolment
06/01/2014

Date of final enrolment
03/10/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Joint Research Compliance Office
London
United Kingdom
W6 8RF

Sponsor information

Organisation
Imperial College London (UK)

Sponsor details
Joint Research Compliance Office
Charing Cross Hospital
Fulham Palace Road
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England
United Kingdom
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Sponsor type
University/education

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
Public Health England (PHE) (UK)

Alternative Name(s)
PHE

Funding Body Type
Government organisation

Funding Body Subtype
National government

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?
HRA research summary			28/06/2023	No	No