

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

Submission date 16/01/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 16/01/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 11/05/2017	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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. Physiandiagnosis 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 =38.0 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

London

England

United Kingdom

W6 8RF

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