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

Submission date	Recruitment status	Prospectively registered
16/01/2014	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
16/01/2014	Completed	Results
Last Edited	Condition category	☐ Individual participant data
11/05/2017	Injury, Occupational Diseases, Poisoning	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Ms Christine Buicke

Contact details

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Additional identifiers

Protocol serial number 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

Study type(s)

Other

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(s)

Immediate allergic reaction (<30mins following administration)

Key secondary outcome(s))

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 years

Upper age limit

17 years

Sex

All

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

United Kingdom

England

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

Sponsor information

Organisation

Imperial College London (UK)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output typeDetailsDate createdDate addedPeer reviewed?Patient-facing?HRA research summary28/06/2023NoNo