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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
Joint Research Compliance Office
Charing Cross Hospital
Fulham Palace Road
London
United Kingdom
W6 8RF
+44 20 7589 5111
c.buicke@imperial.ac.uk

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

Primary study design
Interventional

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

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 type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No