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Early introduction of allergenic foods to induce tolerance in infants

Submission date 06/02/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 31/03/2009	**Overall study status** Completed	
Last Edited 16/12/2022	**Condition category** Other	

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
FSA ref: T07051

Study information

Scientific Title
Randomised controlled trial of early introduction of allergenic foods to induce tolerance in infants

Acronym
EAT (Enquiring About Tolerance)

Study objectives
1. The early introduction of allergenic foods (from three months of age) will induce regulatory mechanisms that result in a reduced level of food allergy by three years of age. The effect on food sensitisation at three years of age will be determined.
2. The early introduction (from three months of age) of allergenic foods into the infant's diet may lead to a reduction in the prevalence of other allergic conditions by three years of age: specifically asthma (including atopic wheeze), eczema, allergic rhinitis (including aero-allergen sensitisation) combined food allergy prevalence (including food sensitization) and the prevalence of combined allergic disease.
3. The early introduction of allergenic foods does not have any deleterious effects

Ethics approval required
Old ethics approval format

Ethics approval(s)
St Thomas' Hospital Research Ethics Committee, 20/10/2008, ref: 08/H0802/93

Study design
Randomised controlled multi-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Food allergy, food hypersensitivity, eczema, asthma, allergic rhinitis

Interventions

The intervention arm consists of the dietetic controlled introduction of allergenic foods from three months of age. Baby rice mixed with breast milk or water will be commenced first, followed by cow's milk based yoghurt. Subsequently egg, wheat, sesame, fish and peanut will be sequentially introduced into the diet in high doses with each food being ingested 2 times a week achieving a total ingestion of 4 g or more per week of each food protein by five months of age.

Mothers will not introduce wheat before 4 months of age. Infants in the intervention arm will be required to consume the allergenic foods until the one-year assessment at which point ongoing consumption of all six allergenic foods will be encouraged until the end of the study when subsequent consumption will be a matter of parental choice.

The control arm will follow standard UK Government weaning advice (exclusive breast feeding until around 6 months of age) and no early introduction of allergenic foods (egg, wheat, peanuts, tree nuts, seeds, fish and shell fish) before six months of age.

Total duration of follow-up: Infant: from 3 months to 3 years of age

Intervention Type
Behavioural

Primary outcome measure
The period prevalence of IgE mediated food allergy to the six intervention foods between one and three years of age in both arms

Secondary outcome measures
1. Period (one to three years of age) prevalence food outcomes:
1.1. The period prevalence of all IgE mediated food allergy between one and three years of age in both arms
1.2. The period prevalence of all food allergy (IgE and non-IgE mediated) between one and three years of age in both arms
1.3. The period prevalence of sensitisation to food between one and three years of age in both arms

2. Cumulative (by three years of age) prevalence food outcomes:
2.1. The cumulative prevalence of IgE mediated food allergy to the six intervention foods by three years of age.
2.2. The cumulative prevalence of all IgE mediated food allergy by three years of age
2.3. The cumulative prevalence of all food allergy (IgE and non-IgE mediated) by three years of age
2.4. The cumulative prevalence of non-IgE mediated food allergy by three years of age
2.5. The cumulative prevalence of sensitization to the six foods by three years of age

3. Other allergic disease outcomes:
3.1. The point prevalence of eczema at one year and three years of age and cumulative prevalence of eczema by three years of age
3.2. The severity of eczema at one year and three years of age by Severity Scoring of Atopic Dermatitis index (SCORAD) and Nottingham Eczema Severity Score (NESS)
3.3. The prevalence of allergic rhinitis at three years of age
3.4. The prevalence of inhalant allergen sensitisation at one year and at three years of age by skin prick test
3.5. The prevalence of inhalant allergen sensitisation at one year and at three years of age by

specific IgE measurement
3.6. The prevalence of the atopic wheeze phenotype at three years of age

4. Composite allergy outcome:
4.1. The prevalence of combined allergic disease (a composite of cumulative IgE mediated food allergy to all foods, atopic wheeze phenotype, eczema and allergic rhinitis) at three years of age
4.2. The prevalence of combined allergic disease (a composite of cumulative IgE and non-IgE mediated food allergy to all foods, atopic wheeze phenotype, eczema and allergic rhinitis) at three years of age

Overall study start date
02/02/2009

Completion date
31/07/2014

Eligibility

Key inclusion criteria
1. Pregnant mothers attending their 12/20 week ultrasound scans
2. Mothers planning on exclusively breast feeding for at least the first 3 months
3. Informed consent obtained from parent or guardian

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
3,000 pregnant women (2,500 infants)

Key exclusion criteria
1. Significant antenatal anomaly at 20 week ultrasound scan
2. Multiple pregnancy
3. Significant congenital disease (enteropathy, congenital heart disease, renal disease)
4. Premature delivery (less than 37 completed weeks gestation)
5. Parents not planning on breast feeding exclusively for at least the first 3 months
6. Parents planning on moving away from London before their child is three years of age
7. Parents unable to speak and read English
8. Unwillingness or inability to comply with study requirements and procedures
9. Family intend infant to be on a restricted diet (any of the six intervention foods)

Date of first enrolment
02/11/2009

Date of final enrolment

30/07/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Thomas' Hospital
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Guy's and St Thomas' NHS Foundation Trust

Sponsor details
R&D Department
3rd Floor, Conybeare House
Great Maze Pond
London
England
United Kingdom
SE1 9RT

Sponsor type
Hospital/treatment centre

Website
http://www.guysandstthomas.nhs.uk/

ROR
https://ror.org/00j161312

Organisation
King's College London (UK)

Sponsor details

Room 1.8
Hodgkin Building, Guy's Campus
London
England
United Kingdom
SE1 1UL

Sponsor type
University/education

Funder(s)

Funder type
Government

Funder Name
Food Standards Agency

Alternative Name(s)
The Food Standards Agency, FSA

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
Medical Research Council (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

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
Not provided at time of registration

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	05/05/2016		Yes	No
Results article	results	06/08/2018		Yes	No
Other publications	Secondary analysis	07/12/2021	09/12/2021	Yes	No
Other publications	Defining the window of opportunity and the target populations to prevent peanut allergy	12/12/2022	16/12/2022	Yes	No