

Measures to Address Maternal Anxiety

Submission date 07/03/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/03/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/02/2016	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Thisanayagam Umasunthar

Contact details
Department of Paediatrics
Wright-Fleming Institute
Norfolk Place
London
United Kingdom
W2 1PG
-
t.umasunthar@imperial.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
9932

Study information

Scientific Title

Measures to Address Maternal Anxiety: a randomised control study

Acronym

MAMA

Study objectives

This is a factorial randomised controlled trial of two different interventions in the same population, to answer two different questions. The first intervention compares two adrenaline auto-injector devices, namely Anapen® and EpiPen®, to evaluate whether one is easier than the other for parents of a food allergic child to learn to use effectively. The second intervention compares two different methods for discussing risks associated with food allergy with mothers of food allergic children, to evaluate their effect on maternal anxiety. 200 mothers with children who have food allergy will be randomised to one of four groups in a 2x2 factorial study design. The primary outcome measure for the comparison of adrenaline auto-injectors is effective delivery of adrenaline in a simulated scenario 6 weeks after training, using a trainer auto-injector device. The primary outcome measure for the informational intervention is maternal state anxiety score 6 weeks after the intervention.

Ethics approval required

Old ethics approval format

Ethics approval(s)

West London Research Ethics Committee 2, ref: REC10/H0711/76

Study design

Randomised interventional process of care

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Topic: Medicines for Children Research Network; Subtopic: All Diagnoses; Disease: All Diseases

Interventions

Adrenaline auto-injector: participants will be randomised to receive training with either Anapen® or EpiPen®.

Informational intervention: participants will be randomised to receive either a new approach to discussing food allergy or current standard of care.

Study Entry: Single Randomisation only

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

State anxiety (STAI) score; Timepoint(s): 6 weeks (primary outcome) and 12 months (secondary outcome)

Secondary outcome measures

Successful administration of adrenaline using a trainer device, judged by an independent observer; Timepoint(s): 6 weeks (primary) and 12 months (secondary)

Overall study start date

28/02/2011

Completion date

02/03/2012

Eligibility

Key inclusion criteria

Pilot phase:

Parents of children attending the paediatric outpatient department at St Mary's Hospital food allergic/atopic/healthy groups categorised according to diagnoses made by the treating clinician. Food allergic group will be limited to those with IgE-mediated food allergy.

Main study:

1. Children aged 0-18 with food allergy (and their mother) diagnosed at a tertiary paediatric allergy clinic and need for adrenaline auto-injector prescription due to risk of anaphylaxis
2. Patient weight = 7.5 kg
3. Ability to converse fluently and read instructions in English or with an appropriate translator

Participant type(s)

Patient

Age group

Child

Upper age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 200; UK Sample Size: 200

Key exclusion criteria

Pilot phase:

Parents of children with known non-atopic chronic diseases likely to impact on maternal anxiety and stress will be excluded from this pilot phase

Main study:

1. Previous training to use an injectable adrenaline device
2. Known psychiatric morbidity such as psychotic disorders which might be expected to impact on the validity and appropriateness of the psychological intervention
3. Poor English language fluency and/or poor reading ability

Date of first enrolment

28/02/2011

Date of final enrolment

02/03/2012

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Wright-Fleming Institute

London

United Kingdom

W2 1PG

Sponsor information

Organisation

Imperial College London (UK)

Sponsor details

School of Medicine

Hammersmith Hospital

Du Cane Road

London

England
United Kingdom
W12 0HS

Sponsor type
University/education

ROR
<https://ror.org/041kmwe10>

Funder(s)

Funder type
Industry

Funder Name
Lincoln Medical (UK)

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?
Results article	results	01/07/2015		Yes	No