ISRCTN29175528 https://doi.org/10.1186/ISRCTN29175528

An investigation of the usability of different adrenaline autoinjector devices

Submission date
08/03/2012

Recruitment status
No longer recruiting

Registration date
14/03/2012

Overall study status
Completed

Last Edited
24/02/2016

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Adrenaline autoinjectors are prescribed for patients at risk of severe systemic allergic reactions (anaphylaxis), most commonly for children with food allergy. Several different devices are available, and patients are sometimes switched from their own device to a new one. It is unclear whether switching a patient from one device to a new one without training them in the new device means that they will be less able to effectively administer adrenaline in the event of anaphylaxis. This study is designed to answer whether 'device switches' without training in how to use the new device are potentially harmful, by decreasing patients' ability to effectively administer adrenaline for treatment of anaphylaxis.

Who can participate:
Participants from the MAMA research study (ISRCTN12504076) who have completed the study.

What does the study involve?
Assessment of whether participants are able to effectively administer adrenaline, using one of several different adrenaline autoinjector devices.

What are the possible benefits and risks of participating?
The benefits are possibly to understand more about severe allergic reactions and their management. The risk is that participation may be slightly stressful, since the scenario-based assessment of adrenaline autoinjector use is quite realistic.

Where is the study run from?
St Marys Hospital, Paddington and Imperial College London (UK)

When is the study starting and how long is it expected to run for?
March 2012 to August 2013

Who is funding the study?
Lincoln Medical, a company that makes adrenaline autoinjectors

Who is the main contact?
Dr Robert Boyle
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Contact information

Type(s)
Scientific

Contact name
Dr Robert Boyle

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
version 13.0 27th January 2012

Study information

Scientific Title
An investigation of the usability of different adrenaline autoinjector devices

Study objectives
In mothers of children with food allergy who were trained to use a specific adrenaline autoinjector device a year ago, the rate of successful adrenaline administration will be lower when using an alternative autoinjector device, than the success rate when using their own device.

Ethics approval required
Old ethics approval format

Ethics approval(s)

West London Research Ethics Committee, 01/03/2012, ref: 0/H0711/76

Study design
Randomised controlled single-centre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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
Food allergy

Interventions
Randomised controlled assessment - subjects will be randomly allocated to have 1 of 4 different types of training assessment, but will not receive any active intervention apart from the assessment.

Participants are randomly allocated to be assessed using 1 of 4 different adrenaline autoinjector devices, which they have not previously been trained to use.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Ability to effectively administer adrenaline using a trainer autoinjector device in a simulated anaphylaxis scenario, assessed by a trained observer.

Secondary outcome measures
Adverse events during simulated anaphylaxis scenario, assessed by a trained observer.

Overall study start date
14/03/2012

Completion date
31/08/2013

Eligibility

Key inclusion criteria
1. Completion of primary and secondary outcome assessments in MAMA trial (http://www.controlled-trials.com/ISRCTN12504076/)
2. Willingness to participate in a further assessment

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
200

Key exclusion criteria
Previous training to use one of the alternative adrenaline autoinjector devices used in this study

Date of first enrolment
14/03/2012

Date of final enrolment
31/08/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Imperial College London
London
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Sponsor information

Organisation
Imperial College London (UK)

Sponsor details
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Sponsor type
University/education

Website
http://www3.imperial.ac.uk/

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Industry

Funder Name
Lincoln Medical Ltd (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