An investigation of the usability of different adrenaline autoinjector devices

Submission date 08/03/2012	Recruitment status No longer recruiting	[X] Prospectively registered		
		☐ Protocol		
Registration date 14/03/2012	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 24/02/2016	Condition category Injury, Occupational Diseases, Poisoning	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 r.boyle@nhs.net

Contact information

Type(s)

Scientific

Contact name

Dr Robert Boyle

Contact details

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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 United Kingdom W2 1PG

Sponsor information

Organisation

Imperial College London (UK)

Sponsor details

South Kensington Campus London England United Kingdom SW7 2AZ

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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