

# An investigation of the usability of different adrenaline autoinjector devices

<b>Submission date</b> 08/03/2012	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 14/03/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/02/2016	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> 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

Imperial College London

Department of Paediatrics

Wright Fleming Building

Norfolk Place

London

United Kingdom

W2 1PG

-

r.boyle@nhs.net

## Additional identifiers

### Protocol serial number

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

**Study type(s)**

Quality of life

**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(s)**

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

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Child

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**

**Imperial College London**

London

United Kingdom

W2 1PG

## **Sponsor information**

**Organisation**

Imperial College London (UK)

**ROR**

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

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

Lincoln Medical Ltd (UK)

# 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?
<a href="#">Results article</a>	results	01/07/2015		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes