

Educating adolescents at Risk of Anaphylaxis

Submission date 17/10/2012	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 18/10/2012	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 26/04/2016	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Neil Davidson

Contact details

Newcastle upon Tyne Hospitals NHS Foundation Trust
Queen Victoria Road
Newcastle Upon Tyne
United Kingdom
NE1 4LP
-
neil.davidson@nuth.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13139

Study information

Scientific Title

Educating adolescents at Risk of Anaphylaxis

Acronym

ERA

Study objectives

Anaphylaxis describes a serious and possibly life-threatening allergic reaction. Food allergy accounts for 85% of reactions in children and risk factors for severity include age (adolescents & young adults) and delayed use of rescue medication adrenaline (epinephrine). In this study, we believe that a teaching programme that is relevant to teenagers, and takes account of their fears and anxieties about the condition, will increase their knowledge, understanding and treatment of allergic symptoms, and in so doing also improve their perceptions of quality of life issues associated with anaphylaxis risk. We aim to invite 80 young people, aged 11-16 years, with confirmed food (nut) allergy and who are prescribed a self-injectable adrenaline autoinjector (SIA) to participate in the study. These patients attend the regional allergy clinic at the Great North Children's Hospital, Royal Victoria Infirmary, Newcastle.

We will compare how the standard clinic education session (control) differs to a novel education package (intervention) in improving patient knowledge, understanding, skill in using autoinjector and quality of life scores. The intervention will involve facilitated discussion, review of videos of simulated anaphylactic reactions and their management, as well as hands-on practice using different SIA devices. Those patients attending the teaching intervention and who have a smartphone will be offered an app that directly supports the session learning points, including prompts to carry and renew medication and guidance to treatment of an anaphylactic reaction. Knowledge, understanding and treatment skills will be assessed by a quiz and demonstration of correct use of SIA device. Quality of life perceptions will be assessed by a questionnaire. Participant views about the teaching intervention will be collected by session evaluation questionnaires and semi-structured interview.

Ethics approval required

Old ethics approval format

Ethics approval(s)

First MREC, 10 January 2012 ref: 11/EE/0530

Study design

Randomised interventional trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

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

Anaphylactic shock in paediatrics

Interventions

Education Session:

A face-to-face teaching session involving discussion groups; video demonstration of (simulated) anaphylactic reactions and management; demonstration and practice with adrenaline SIAs; knowledge & skill assessments.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Knowledge & skills measured at study entry, at end of education session and at follow-up (3 months after session)

Secondary outcome measures

1. Carriage of SIA device, measured at study entry and follow-up (3 months)
2. Impact of smartphone app measured at follow-up - self-reported and correlated with knowledge / skills / QoL.
3. Quality of life measured at study entry and at follow-up (3 months)

Overall study start date

05/11/2012

Completion date

07/06/2013

Eligibility

Key inclusion criteria

1. Be a young person aged 11-16 years (inclusive)
2. Be a patient of the Great North Children's Hospital regional allergy clinic
3. Have confirmed food (nut) allergy
4. Have been prescribed an adrenaline self-injectable autoinjector device
5. Speak and understand written and spoken English
6. Male or female participants

Participant type(s)

Patient

Age group

Child

Lower age limit

11 Years

Upper age limit

16 Years

Sex

Both

Target number of participants

UK Sample Size: 80; Description: 40 in intervention group 40 controls

Key exclusion criteria

1. Must not have another (non-allergic/ atopic) chronic medical condition
2. Regarded by parent/carer as not yet capable of supported, independent allergy care
3. Unable to speak and/or understand written and spoken English

Date of first enrolment

05/11/2012

Date of final enrolment

07/06/2013

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Newcastle upon Tyne Hospitals NHS Foundation Trust

Newcastle Upon Tyne

United Kingdom

NE1 4LP

Sponsor information**Organisation**

Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

Sponsor details

New Victoria Wing

Queen Victoria Road

Newcastle Upon Tyne

England
United Kingdom
NE1 4LP

Sponsor type

Hospital/treatment centre

Website

<http://www.newcastle-hospitals.org.uk/>

ROR

<https://ror.org/05p40t847>

Funder(s)

Funder type

Industry

Funder Name

ALK - Abello LTD (UK)

Funder Name

Allergy Therapeutics (UK)

Funder Name

Meda AB (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