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Educating adolescents at Risk of Anaphylaxis

Submission date	Recruitment status	[X] Prospectively registered
17/10/2012	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
18/10/2012	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/04/2016	Injury, Occupational Diseases, Poisoning	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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