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24 hour parental access to expert anaphylaxis management advice

Submission date	Recruitment status	[X] Prospectively registered
20/06/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
16/08/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/04/2017	Injury, Occupational Diseases, Poisoning	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Anaphylaxis is a severe and potentially life-threatening reaction to a trigger such as an allergy. Outside of hospital, food allergies are the most important triggers of anaphylaxis in children. People with potentially serious allergies are often given an adrenaline auto-injector to carry at all times, which can help stop an anaphylactic reaction becoming life threatening. However, many families struggle to comply with instructions and there is often a delay or a failure to administer adrenaline in cases that have sadly ended with a fatal outcome. Parents of children with food allergies report uncertainty in relation to "what is going to happen next time", which contributes to anxiety and low quality of life. This is because families are generally on their own and remote from medical help when they need to make the decision about whether or not to use the adrenaline auto-injector. They may be uncertain if the reaction is severe enough to warrant using the autoinjector or they may be worried that their child may come to harm if given adrenaline when the reaction was not severe. Most clinical services encourage families to treat early: if in doubt give the adrenaline, as delay can worsen the outcome. However, this is a difficult decision for parents to make, even in a life-threatening scenario. The aim of this study is to find out whether 24 hour availability of expert advice from a Paediatric Allergy team via telephone improves the quality of life of families living with food allergy.

Who can participate?
Parents of patients aged up to 16 attending the Paediatric Allergy Clinic in Cork University Hospital (CUH), prescribed and trained in the use of adrenaline auto-injectors for serious food allergy

What does the study involve?
Participating families are randomly allocated to receive 24 hour access to expert support or to receive routine care. At the start of study and after 1 month and 6 months (end of study) all families complete a quality of life questionnaire. The number of A&E/hospital attendances, use of adrenaline auto-injector in an emergency, and inappropriate calls to the helpline are also assessed.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University College Cork (Ireland)

When is the study starting and how long is it expected to run for?
September 2011 to May 2012

Who is funding the study?
University College Cork (Ireland)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
-

Study information

Scientific Title
24 hour parental access to expert anaphylaxis management advice: a prospective, blinded, pragmatic effectiveness trial

Study objectives
24 hour access to expert advice via telephone will improve quality of life for families living with food allergy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Clinical Research Ethics Committee Cork Teaching Hospitals, UCC, 30/05/2011, ref: ECM3 07/06 /11

Study design
Prospective blinded pragmatic effectiveness trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Anaphylaxis, food allergy

Interventions
Provision of 24 hour telephone access to expert allergy clinic staff to assist in family decision to use or not use adrenline autoinjectors in the setting of an unanticipated allergic reaction.

50 families will be randomised to I (Intervention) or R (Routine) care. Intervention group will receive a telephone number that will be open 24/7 for 6 months, giving access to expert advice in the case of an allergic reaction. Routine arm will not be given this number. Food Allergy Quality of Life (FAQL) will be measured before randomisation and at 1 month and 6 months post randomisation.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

The difference/relative change in quality of life between Intervention and Routine care arms, on an intention-to-treat basis at 6 months

Secondary outcome measures
1. Difference in Food Allergy Quality of Life (FAQL) at 1 month post randomisation
2. Incident reports (number of accident & emergency [A&E]/hospital attendances, use of adrenaline auto-injector in an emergency, inappropriate calls to the helpline)

Overall study start date
01/09/2011

Completion date
31/05/2012

Eligibility

Key inclusion criteria
1. Parents of newly referred and exisiting patients (up to 16 years) attending Paediatric Allergy Clinic in Cork University Hospital (CUH)
2. Families trained by CUH clinc staff and demonstrating competence in use of adrenaline autoinjectors to treat anaphylaxis

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Key exclusion criteria
Familes who do not complete satisfactory CUH training in use of adrenaline autoinjectors to treat anaphylaxis

Date of first enrolment
01/09/2011

Date of final enrolment
31/05/2012

Locations

Countries of recruitment
Ireland

Study participating centre
University College Cork
Cork
Ireland
N/A

Sponsor information

Organisation
University College Cork (Ireland)

Sponsor details
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Sponsor type
University/education

Website
http://www.ucc.ie/en/

ROR
https://ror.org/03265fv13

Funder(s)

Funder type
University/education

Funder Name
University College Cork

Alternative Name(s)
Coláiste na hOllscoile Corcaigh, UCC

Funding Body Type
Private sector organisation

Funding Body Subtype

Universities (academic only)

Location
Ireland

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