Training food-allergic patients to use their epinephrine auto-injector: a pilot study

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Primary Objective:The primary objective of this study is to test the feasibility of methods and procedures prior to performance of a full-scale research project.Secondary Objective(s):The secondary objectives of this study are to determine whether...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Allergic conditions
Study type	Interventional

Summary

ID

NL-OMON44075

Source
ToetsingOnline

Brief title
SEPI training

Condition

- Allergic conditions

Synonym
anaphylaxis, food-allergy

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: anaphylaxis, epinephrine auto-injector, food-allergy, quality of life

Outcome measures

Primary outcome

The main study parameter is to test the feasibility of methods and procedures prior to performance of a full-scale research project.

Secondary outcome

The secondary study parameters of this study the possible difference (improvement or deteroriation) between HRQL, the measured burden of treatment of an EAI, perceived disease severity and anxiety and confidence with an EAI on both measuring time points (baseline and follow-up) between (a) children (aged 8-12 years) and their parents who did self-administer an EAI and (b) children (aged 8-12 years) and their parents who did not selfadminister an EAI (age group 1). And also, between (c) teenagers (aged 13-17 years) and their parents who did self-administer and EAI and (d) teenagers (aged 13-17 years) and their parents who did not self-administer an EAI (age group 2).
A difference in total FAQLQ scores of >=0.5 points will be considered to be a clinically relevant difference (=minimal important difference (MID)). The difference in total FAQLQ score between both measuring points (baseline and follow-up) will be compared with the GRCscore, to identify which increase or decrease in FAQLQ score corresponded to the score of minimal important change on the GRC(34,35). If there is a significant improvement in HRQL, this will be used for calculating a number needed to treat (NNT) of prescribing an EAI to food

allergic patients.

Study description

Background summary

Currently, the only treatment for food allergy is avoidance of the culprit food and the provision of an epinephrine auto-injector (EAI) in emergency situations(1). Living with the need to avoid the culprit foods, living in fear of allergic reactions and having to carry an epinephrine auto-injector at all times may interfere with daily life of food-allergic children and adolescents, and their families. Consequently, an accurate diagnosis is very important in order to identify which foods should be avoided, followed by proper patient education.
Previous studies repeatedly stress that there is a need for better education of food-allergic patients and their parents concerning instructions about when and how to the use of EAI. Using self-administration of an EAI (when needed) as a didactic tool (training program) may be more effective in alleviating fear and uncertainty incurred by the prospect of using the device. This may, in turn, lead to improved HRQL. It is therefore of interest to ascertain whether EAI self-administration does indeed have these effects.

Study objective

Primary Objective:
The primary objective of this study is to test the feasibility of methods and procedures prior to performance of a full-scale research project.

Secondary Objective(s):
The secondary objectives of this study are to determine whether HRQL, burden of treatment (BoT) of an EAI, anxiousness and confidence using an EAI of food-allergic patients improves by undergoing a training program including administering an EAI to themselves (or being administered by a parent) during a routine DFPCFC resulting in an allergic reaction. A difference in total FAQLQ scores of >=0.5 points will be considered to be a clinically relevant difference (=minimal important difference (MID)).

Study design

This pilot study is a prospective randomized pilot study, with an estimated inclusion time of six months (February 1st, 2015 until July 31st, 2015).

Intervention

Self-administration of an EAI during a DBPCFC resulting a objective allergic symptoms.

Study burden and risks

Patients meeting all inclusion criteria without meeting any exclusion criteria will be eligible for randomization. Patients who visit our FCU and who enter the study potentially benefit from the self-administration of an EAI during a routine DBPCFC resulting in objective
allergic symptoms. The routine DBPCFC takes place on two different days, therefore they will visit the hospital on two occasions.
After self-administration of an EAI (when needed) the patient may feel more confident and empowered to use their own EAI if needed and without hesitation. This may, in turn, lead to improved HRQL. Transient pharmacologic effects of epinephrine, such
as pallor, tremor, anxiety, palpitations, headache, and dizziness, that occur within 5 to10 minutes after injection are usually mild and confirm that a therapeutic epinephrine dose has been given.
Serious adverse effects are rare with intramuscular use, and are usually attributable to epinephrine overdose, which is unlikely to happen
when using an auto-injector with a single fixed dose of epinephrine.

The burden of the online questionnaire-packages is low, the time requested is less than 15 minutes. Patients are asked to complete twice an online questionnaire-pakcage; the total time requested is 30 minutes. The burden will be minimal due to extensive
experience in our FCU with DBPCFCs. Nevertheless, we are aware, that the outcome of the DBPCFC is unpredictable and reactions may occur in patients.

The study can only be done in this group of children (aged <18 years) because we find high numbers of sensitization and atopy in children. Also, adolescents in particular are the age-group with the highest risk for food allergy fatalities.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700RB
NL

Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700RB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

- Food-allergic children and adolescents (aged 8-17 years) being suspected of a food allergy requiring an epinephrine auto-injector
- Above mentioned patients undergoing a routine double blind, placebo-controlled food challenge in our food challenge unit.
- Never self-administered an epinephrine auto-injector.
- Informed consent obtained from parent / guardian or participant, as appropriate.

Exclusion criteria

Food-allergic children < aged 8 years or >17 years.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-03-2015
Enrollment:	52
Type:	Actual

Ethics review

Approved WMO

Date:	14-03-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL52053.042.15