Selective Gamba Food Allergy

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

Summary

ID

NL-OMON40523

Source
ToetsingOnline

Brief title
Gamba study

Condition

- Allergic conditions

Synonym
Food allergy, IgE mediated allergy

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Allergy, Food, Gamba, OFC

Outcome measures

Primary outcome

Positive open challenge with Gamba and Shrimp

Secondary outcome

Presence of gamba specific allergens

Study description

Background summary

Allergy to seafood is a common problem. The main allergen of shrimp and related shellfish is tropomyosin. Tropomyosin is responsible for cross-reactivity between dust mites and seafood.(Arthropodas) Because of this cross-reactivity patients with an allergy to shrimp are advised to avoid all shellfish. Sporadically, patients are seen with an allergy to gamba withouta clear-cut allergy to dust mite. Cross-reacting allergens seem to play no role here. In recent years, although several other shellfish allergens have been identified, it is not yet clear which of all play a role in allergy to gamba's. Since the etiology of gamba's is still not entirely clear, it is impossible to predict reactions of these patients to other crustaceans. Till now the general advice in these patients is avoidance of all crustaceans which might not be necessary.

Study objective

The aim of the study is to identify patients with selective gamba-allergy and sensitization patterns for the various allergens in gamba extracts. Comparing sensitization patterns between patients who clinically react to Gamba with patients having a house dust mite allergy combined with a shrimp allergy, will hopefully give us more understanding of the clinical relevance of cross-sensitization between gamba and shrimp and the molecular basis of it. Furthermore, we want to investigate whether the specific allergic reaction to gamba is caused by the presence of IgE-antibodies against proteins in the gamba, without IgE against possible cross reacting allergens.

Study design

Descriptive case study, focused on patients with selective gamba-allergy as well as patients with a non-selective shrimp allergy. The first step is to identify patients with selective gamba allergy on the basis of diagnostic

research (skin tests and oral provocation). This research takes place at the Department of Allergology, Erasmus MC. the second step is to compare sensitization patterns against gamba and shrimp proteins between patients with selective gamba-allergy, respectively a non selective shrimp allergy. The associated laboratory research takes place at Wageningen University & Research Centre.

Intervention

nvt

Study burden and risks

Group 1:

3 visits in the Hospital of which 1 x 1 hour and 2 x 5 hours

1st visit: inf concent signs, specific food history, blood collection, skin prick test

2nd visit: 1st open provocation

3rd visit: 2nd open provocation

Group 2:

1 visit: 1 x 1 hour

Inf concent signs, specific food history, blood collection, skin prick test

At the skin test wheal may occur on the site of the prick, which, after some hours disappears.

A blood collection (20 ml) usually gives no risks.

2 x open provocation (one with gamba and one with shrimp) on two different days. After the last provocation the result will be discussed.

A provocation brings risks, but the risk for the patient will be limited given the extensive experience in the field of Allergology at the outpatient clinic with food provocations. The provocation starts at a very low dosage. (1 mg scale animal protein) All the required facilities are provided (emergency

medication, adequate medical personnel). The provocation is carried out according to international guidelines.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Group 1:
Patients (adults >18 years) with a possible selective gamba allergy without housedustmite allergy and without complaints after eating shrimps.
Group 2:
Patients (adults >18 years) with a housedustmite allergy en a possible non selective allergy voor shrimps

Exclusion criteria

Group1:
Severe or uncontrolled asthma and/or recent (< 1 year) intensive care unit admissions. Severe eczema defined as TIS (Three Item Severity) eczema score (> 6). Severe psychosocial problems. Not able to stop anti-histamine medication for a short period. Use of beta-blockers. patients (adults) unable to stop anit-histaminica and/ or B- blokkers. Patients with medicins that cannot be combined with oral food challenge.e.g. Prednison, cyclosporine en montelukast.
Pregnancy
Group 2:
Severe eczema defined as TIS (Three Item Severity) eczema score (> 6). Severe psychosocial problems. Not able to stop anti-histamine medication for a short period.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-12-2014
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	24-02-2014

Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL47225.078.13