Immunological assays as useful tools in the study of sesame seed allergy

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To study the validity and usefulness of three immunological assays to improve knowledge on the course and diagnosis of sesame seed allergy in sesame seed allergic patients with proven anaphylaxis. In the first place, the CAP inhibition assay is used...

Ethical review	Approved WMO
Status	Pending
Health condition type	Allergic conditions
Study type	Observational non invasive

Summary

ID

NL-OMON37245

Source
ToetsingOnline

Brief title
IAISSA (Immunological Assays In SesameSeed Allergy

Condition

- Allergic conditions

Synonym
Sesame seed allergy

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: eigen middelen

Intervention

Keyword: Allergy, BAT, CAP-inhibition, Sesame seed

Outcome measures

Primary outcome

BAT: Upregulation of CD-63 on basophils, converted to the percentage activated basophils. CAP: Percentage inhibition, calculated by amount of sIgE bound to CAPs. Immunoblot: Thickness of protein bands visible on the Immunoblot (kDa).

Secondary outcome

NVT

Study description

Background summary

Sesame seed anaphylaxis is potentially life-threatening. Patients need to have life-long dietary restrictions and emergency medication, which is often a social burden for these patients. Accurate diagnosis is necessary, to prevent redundant dietary restrictions. The golden standard for diagnosis of food allergy is the double-blind, placebo-controlled food challenge, which is potentially dangerous and expensive. Alternative diagnostic methods are serum specific Immunoglobulin E (IgE) testing and skin prick tests (SPTs). However, these tests can give high numbers of false positive results. Another promising method in the diagnosis of food allergy is the basophil activation test (BAT). The number of studies investigating this method in relation to sesame seed allergy in particular is limited. More research is needed to confirm the usefulness of BAT and to improve the testing procedure. In addition, to study the course of sesame seed allergy, application of immunoblotting and the immunological assay CAP inhibition could be useful. Until now, the relatively new method of CAP inhibition is only tested on fig allergens. Therefore, more research should be aimed at investigating these assays to improve knowledge on the course and diagnosis of sesame seed allergy.

Study objective

To study the validity and usefulness of three immunological assays to improve knowledge on the course and diagnosis of sesame seed allergy in sesame seed

allergic patients with proven anaphylaxis. In the first place, the CAP inhibition assay is used to study the primary sensitization allergen in these sesame seed allergic patients. Secondly, the immunological assay BAT is tested for its reliability in the diagnosis of sesame seed allergy. Finally, the Immunoblot is used to investigate the sesame seed specific IgE profile of the patient and the potential relationship with the atopic profile and clinical history.

Study design

Observational pilot study.

Study burden and risks

Participants will have to donate a small amount of blood once. The burden and risks associated with participation are negligible.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Philips van Leydenlaan 15
Nijmegen 6525 EX
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Philips van Leydenlaan 15
Nijmegen 6525 EX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

known sesame seed allergy (medical history and sIgE detection by Skin test or RAST).

Exclusion criteria

Age below 15.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2012
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Date:	15-01-2013

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL42526.091.12