

Comparative research between results of skin prick tests and prick to prick tests performed with fruit and vegetable extracts.

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1. Are the results of the skin prick test (SPT) performed with homemade extracts and the prick-to-prick test (PTP) with fruit and vegetables comparable? 2. Is there a difference in sensitivity and/or specificity between the SPT and PTP with fruit and...

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

Summary

ID

NL-OMON51704

Source

ToetsingOnline

Brief title

HoMaFA-2

Condition

- Allergic conditions

Synonym

food allergy, food hypersensitivity

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: allergen specific IgE, food allergy, prick to prick test, skin prick test

Outcome measures

Primary outcome

The results of skin tests performed as a skin prick test (SPT) are comparable to the results of skin tests performed as a prick to prick test (PTP).

Secondary outcome

The results of both skin test methods (SPT and PTP) are comparable with the specific allergic complaints reported in the questionnaire.

The results of both skin test methods (SPT and PTP) are comparable to the measured serum IgE .

Study description

Background summary

Homemade extracts of foods have been made in the Erasmus Medical Center for some time now (mid-nineties), which are used in the diagnosis of an IgE-mediated food allergy. The skin tests performed with these extracts are a fast, reliable and cheap method to confirm sensitization in the patient. Over the years, less food allergens have been commercially available, and are usually not registered. The specificity and sensitivity of the allergens that are still available is usually unknown. As Department of Allergology, we are highly dependent on the homemade extracts when diagnosing a suspected food allergy. For the food allergen extracts that are used, finding the most reliable way of performing the skin test (as a skin prick test with homemade extract, or as a prick-prick test with the fresh food) is of great importance.

Study objective

1. Are the results of the skin prick test (SPT) performed with homemade extracts and the prick-to-prick test (PTP) with fruit and vegetables comparable?

2. Is there a difference in sensitivity and/or specificity between the SPT and PTP with fruit and vegetables, compared to specific food allergic complaints answered in the questionnaire?
3. Is there a difference in SPT and PTP test results compared to measured serum IgE levels in the patient's blood?

Study design

During performing the skin tests, 2 methods are compared in participants of the study; the skin prick test (SPT) with homemade extracts of fruit and vegetables and the prick to prick (PTP) with fresh fruit and vegetables. We test 5 allergens, namely apple, kiwi, peach, tomato and carrot, in the same patient. The skin tests are performed on the forearm, the reactions are measured and scanned after 15 minutes. The HEP (histamine equivalent prick test) index is used. The questionnaire regarding food-related complaints after eating apple, kiwi, peach, tomato and carrot is completed.

A tube of blood (8 ml) is taken from the patient to determine the allergen-specific serum IgE.

Study burden and risks

After assessment of the health question in the referral letter, the patient will receive the information letter about the study, together with the invitation for the first visit to the allergist. The patient will be given enough time to consider taking part in the study. During the first visit to the allergist, the patient will have the opportunity to ask questions, and will be asked to participate in the study.

The visit will take approximately 1 hour. 5 food allergens will be double tested when participating; as skin prick test (SPT) with homemade food allergens, and prick to prick test (PTP) with fresh food. We will test apple, kiwi, peach, tomato and carrot.

As a result of the skin test, a little red itchy bump may develop at the site of the test, the forearm, which is at its worst after 15 minutes and then disappears spontaneously. If the patient experiences too much itching, in consultation with the allergist, an antihistamine can be given. A questionnaire about the diet-specific history will be completed, which will take approximately 10 minutes. A tube of blood (8 ml) will be collected by means of a venipuncture. After collecting blood, a bruise may occur, which will disappear spontaneously within 1 week.

Contacts

Public

Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molenwaterplein 40
Rotterdam 3015 GD
NL

Scientific

Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molenwaterplein 40
Rotterdam 3015 GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Inclusion criteria

16 years of age or older, mentally competent
Patients suspected for food allergy
Signed informed consent

Exclusion criteria

Antihistamines used in the last 72 hours before de skin test.
Eczema present on the skin, namely the arm.
Unable to discontinue corticosteroid containing creams/ointment on the skin
(the last 3 day's before the skin test).
Use of more than 10 mg prednisone (relative contraindication).

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 02-01-2023

Enrollment: 69

Type: Anticipated

Ethics review

Approved WMO

Date: 27-12-2022

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

CCMO

ID

NL81413.078.22