Comparative research by means of skin prick test and provocation test between hypo allergenic Migo pear and Conference pear in patients with allergy to pear.

Published: 01-10-2019
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Consuming Migo pear without getting allergic symptoms.

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

Summary

ID

NL-OMON48489

Source
ToetsingOnline

Brief title
Migo pear

Condition

- Allergic conditions
- Food intolerance syndromes

Synonym
allergy, Food hypersensitivity

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Wageningen Food & Biobased Research

Intervention

Keyword: allergy, food challenge, pear, skin prick test

Outcome measures

Primary outcome

Consuming the hypoallergenic Migo pear without experiencing an allergic

reaction.

Secondary outcome

2. How does the amount of pear, at which the patient experience symptoms,

differ between the Migo pear and the Conference pear?

3. What is the difference in surface area in the skin test between the Migo

pear and the Conference pear?

4. What is the difference in surface area in the skin test between the Migo

pear and Birch pollen?

Study description

Background summary

The European Fruit Co-operation (EFC) and Green star-Kanzi Europe NV (GKE NV) have expressed interest in introducing a hypoallergenic pear crop on the market. GKE NV is the variety manager of two world famous apple brands; Kanzi and Greenstar, as well as the pear brand Migo. Some customers who have an apple allergy, indicate they can eat the Migo pear without it causing allergic reactions. Wageningen Food & Biobased Research carried out a literature study on the already completed project *Migo hypoallergenic pear* to describe background information which will be required to determine the feasibility of conducting a claim as hypoallergenic pear crop. EFC and GKE NV have expressed

interest to carry out a humane study (skin prick test and prick to prick test and oral provocation test) to test the hypoallergenic properties of Migo pear in people.

Study objective

Consuming Migo pear without getting allergic symptoms.

Study design

Observational study with interventions.

Study burden and risks

All participating patients will be administered a questionnaire about the diet specific history. On day one, a skin test (SPT and PTP) will be carried out. A single tube of blood will be collected. The patient will visit the hospital twice for 4 hours for an open provocation with pear, which takes place at the Allergy Department. A provocation involves risks, but these risks are limited by starting with the minimal amount of the allergen. The dosage will be increased gradually. Physical complaints are monitored through a VAS score list, related to rating provocation (version 14-12-2018). There always will be a doctor and a nurse present at the Department, emergency medications (antihistamines, dexamethasone and adrenaline) are syringe ready. Possible advantage of participation is the possibility to add pear to the often limited diet or a better estimate of the amount of pear that can be eaten.

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

Signed informed consent form
18 years of age or older, mentally competent
Patients proven allergic to pear by skin prick test and prick to prick test (HEP > 0,4)
Diet free of pear, earlier complaints after eating pear.
No use of antihistamines in the last 72 hours before the skin test and the food challenge with pear.

Exclusion criteria

Patiënt under 18 years, mentally incompetent.
Negative skin prick test and prick to prick test with pear (HEP < 0,4).
Diet not free of pear, eating pear without complaints.
Unable to stop beta blocker
Use of antihistamines in the last 72 hours before the skin prick test and food challenge with pear
Use of more than 10 mg prednisone (relative contraindication)

Study design

Design

Study type: Observational invasive
Masking: Single blinded (masking used)

Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2019
Enrollment:	15
Type:	Anticipated

Ethics review

Approved WMO

Date:	01-10-2019
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	NL70165.078.19