

# Identification of low allergenic apple cultivars and assessment of proper chain conditions in view of apple allergy

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Identification of low allergenic apple cultivars and breeding germplasm  
Identification of chains in which low allergenicity is preserved and of the critical steps in the chain for preserving low allergenicity.

|                              |                     |
|------------------------------|---------------------|
| <b>Ethical review</b>        | Approved WMO        |
| <b>Status</b>                | Pending             |
| <b>Health condition type</b> | Allergic conditions |
| <b>Study type</b>            | Interventional      |

## Summary

### ID

NL-OMON30093

### Source

ToetsingOnline

### Brief title

Low allergenic apple cultivars

### Condition

- Allergic conditions

### Synonym

apple allergy, oral allergy syndrome

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen

**Source(s) of monetary or material Support:** Europese Unie

## Intervention

**Keyword:** apple, food, hypoallergenicity

## Outcome measures

### Primary outcome

Scoring of subjective symptoms of OAS on a VAS-scale by patients

Scoring of objective symptoms, if occurring, on a symptom scale, grading 1 - 3,  
by the physician

### Secondary outcome

not applicable

## Study description

### Background summary

Apple allergy frequently occurs among older children and adults in the Dutch population. The prevalence of apple allergy in Northern and Central Europe is up to 2%.

Apple allergy causes Oral Allergy symptoms (OAS) which is clinically presented by mild symptoms in the oral cavity immediately following consumption of fresh, unprocessed apple.

Apple allergy occurs in concordance with birch pollen allergy ( e.g. in the Netherlands), which can be explained by cross-reactivity of IgE-antibodies between birch pollen allergens (Bet v 1) and apple allergens (Mal d 1).

In patients suffering from severe OAS symptoms almost all fresh fruits cause allergic symptoms. This may affect the nutritious value of the diet and health of patients suffering from OAS symptoms in a negative way.

Low allergenic apple cultivars could be an alternative for apple allergic people

The study from Bolhaar et al, and previously performed research in the UMCG showed that the allergenicity of apple cultivars differs strongly.

The ISAFRUIT project is an integrated research project, which is initiated and funded by the European Union, aiming at increasing fruit consumption among Europeans.

This project is part of ISAFRUIT.

## **Study objective**

Identification of low allergenic apple cultivars and breeding germplasm  
Identification of chains in which low allergenicity is preserved and of the critical steps in the chain for preserving low allergenicity.

## **Study design**

Interventie onderzoek onder appel-allergische proefpersonen, waarbij gebruik wordt gemaakt van huidtests en open voedselprovocatie onderzoek

Intervention study in apple allergic patients, using skin prick tests by prick to prick tests, and open food challenge tests.

## **Intervention**

year 1:

apple cultivars are tested by SPT (prick to prick)

year 2:

oral challenge tests using least allergenic apple cultivars as well as 1 allergenic cultivar.

breeding germplasms tested by SPT (prick to prick)

year 3:

least allergenic apple cultivars coming from different chains are tested by SPT (prick to prick)

year 4:

GMO Mal d 1 knocked down apple cultivars are tested by SPT

oral challenge tests using GMO Mal d 1 knocked down apple cultivars as well as 1 allergenic cultivar

## **Study burden and risks**

Burden of the patient:

Assuming the patients participate in all parts of the study, the extent of the participation is, divided over 4 years:

16 x skin prick tests (lasting 1,5 uur) = 24 hours

3 x oral food challenge (lasting 4 uur) = 12 hours

total: 36 hours

The patients come to the outpatient clinic of the UMCG during 19 times

The number of hours spent on this research project by the patient decreases

along with a decreasing participation in the project.

Possible benefits for the patient:

Identification of low allergenic apple cultivars allows for adding new fruits into the diet of patients.

## Contacts

### Public

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Postbus 30.001  
9700RB Groningen  
NL

### Scientific

Universitair Medisch Centrum Groningen

Postbus 30.001  
9700RB Groningen  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

age 18 and above

anamnestisch oral allergy symptoms following eating fresh apple

positive open food challenge with reference apple cultivar

## Exclusion criteria

absence of anamnestic oral allergy symptoms following eating fresh apple  
negative open challenge with reference appel cultivar  
generalised or systemic symptoms following eating fresh apple  
pregnancy

## Study design

### Design

|                  |                         |
|------------------|-------------------------|
| Study phase:     | 2                       |
| Study type:      | Interventional          |
| Masking:         | Open (masking not used) |
| Control:         | Uncontrolled            |
| Primary purpose: | Treatment               |

### Recruitment

|                           |             |
|---------------------------|-------------|
| NL                        |             |
| Recruitment status:       | Pending     |
| Start date (anticipated): | 01-06-2006  |
| Enrollment:               | 80          |
| Type:                     | Anticipated |

## Ethics review

|                    |   |
|--------------------|---|
| Approved WMO       |   |
| 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**

| <b>Register</b> | <b>ID</b>      |
|-----------------|----------------|
| CCMO            | NL11846.042.06 |