Peanut protein detection in serum

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The primary objective is to set-up a well-defined sandwich ELISA method to measure the levels of Ara h6 in blood after peanut consumption.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malabsorption conditions
Study type	Interventional

Summary

ID

NL-OMON43466

Source
ToetsingOnline

Brief title
PEANUTS Pilot

Condition

- Malabsorption conditions
- Allergic conditions

Synonym
intestinal permeability, Nutrient uptake

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Ara h6, Intestinal permeability, Peanut

Outcome measures

Primary outcome

The primary parameter of the pilot study is the number of subjects in which Ara

h6 in serum can be detected with the sandwich ELISA after peanut consumption

Secondary outcome

The secundary parameter of this pilot study are serum factors that could

possibly influence the sensitivity of the analysis method, such as total peanut

IgE and IgG(4)

Study description

Background summary

Since the exponential increase in the prevalence of food allergies, studies in this field have also increased exponentially. In order to support this research, well-defined and validated methods for measuring these allergens are needed. Currently, there is no such method sensitive enough to detect Ara h6 in the circulation after peanut consumption. Therefore, developing this method would be a valuable tool in the field of food allergies.

Study objective

The primary objective is to set-up a well-defined sandwich ELISA method to measure the levels of Ara h6 in blood after peanut consumption.

Study design

Within this pilot study, participants are requested to come to the university twice. First for a short screening visit (questionnaire and height/weight measurement). For the test day participants will again come to the university, while fasted overnight, to consume 100grams of peanuts. Prior to (baseline) and after intake (30, 60, 120, 240, 360min) of the peanuts, blood will be samples via a venflon cannula. at the end, the participants will receive lunch.

Intervention

Intake of 100 grams of peanuts

Study burden and risks

Subjects need to fill out a screening questionnaire and height/weight are measured. The subjectshave to keep some dietary guidlines, such as no peanut consumption two days prior to test day. Blood withdrawal could lead to minor bruising and stiffness of the arm, and is minimalized by using a venflon canula.Per test day, a total of 72mL blood will be sampled at regular intervals during six hours. Overnight and during these six hours after peanut intake, subjects are not allowed to eat anything else. Seen the caloric density (Equals four cheese sandwiches) and satiating effect of the peanuts, this burden will be small.

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

- 20-35 year old males and females
- Body Mass Index (BMI) 18.5-25 kg/m2
- Suitable veins for blood sampling

Exclusion criteria

- History of peanut allergy
- Known symptoms of immune disease, such as diabetes, gastritis, and coeliac disease.
- Known symptoms of intestinal disease, such as Crohn*s Disease, ulcerosis, and irritable bowel syndrome.
- Smoking
- Use of hard drugs
- Use of specific drugs: Chronic use of NSAIDs: aspirins, ibuprofen, etc.
- Drugs having an effect on gastric and/or intestinal function and motility, including antidepressants
- Participation in other scientific studies (with the exception of EetMeetWeet)
- Blood donation during the last six weeks before the start of the study

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-02-2016
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	29-01-2016
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

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	NL55953.081.15