

Peanut protein detection in serum and exercise

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

Summary

ID

NL-OMON43051

Source

ToetsingOnline

Brief title

PEANUTS Study

Condition

- Gastrointestinal conditions NEC
- Allergic conditions

Synonym

intestinal permeability, nutrient absorption

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, Exercise, Intestinal permeability, Peanuts

Outcome measures

Primary outcome

The primary outcome is the serum Ara h6 level after intake of peanuts with and without exercise

Secondary outcome

The secondary outcome is the lactulose/rhamnose ratio in plasma after intake of the dual sugar solution with and without exercise

Study description

Background summary

Since the exponential increase in the prevalence of food allergies, the number of studies in this field have also increased exponentially. In order to support this research, well-defined methods for measuring allergens are needed. Recently, we developed an ELISA method for the detection of Ara h6 in blood after peanut consumption.

Exercise is known to increase intestinal permeability and it is hypothesized this could possibly lead to increased levels of (partly) digested dietary proteins, thus allergens also, could end up in the bloodstream.

Study objective

The objective of this study is to analyse the effect of exercise on the levels of Ara h6 in the blood after peanut consumption. Next to this we would like to know whether these levels found are associated with the measure of intestinal permeability, which we can measure with the double-sugar test.

Study design

In this study with a crossover design subjects are requested to come to the university while fasted overnight to consume peanuts and a dual sugar solution. On the second test day these consumptions will be followed by a cycle test consisting of steady state cycling for 1 hour at 75% Wmax (Which will be assessed

with a maximal cycling test during the pre-testing). Prior to (baseline) and 30-60-90-120-240min after intake of peanuts and dual sugar solution, blood will be collected via a venflon cannula. At the end of each test day, the subjects will receive lunch.

Intervention

Intake of 100grams of peanuts and a dual sugar solution (5gr lactulose and 1 gr rhamnose), whether or not followed by a cycling test (1 hour 75% Wmax)

Study burden and risks

Subjects need to fill out a screening questionnaire and height and weight are measured. Next to this a fasted blood sample will be drawn to test for an inhibitory matrix effect in the Ara h6 ELISA method. Furthermore they need to complete a maximal cycling test during pre-testing, and 1 hour of steady state cycling at 75% of their Wmax during the second test day.

The exercise intensity is adapted to individual capacity and could at most lead to some muscle fatigue and soreness afterwards. The subjects have to keep some dietary guidelines. Blood withdrawal could lead to minor bruising and stiffness of the arm, and is minimized by using a venflon canula. Per test day, a total of 72mL blood will be samples at regular intervals during approximately 5 hours, making 144mL in total.

Contacts

Public

Wageningen Universiteit

Bornse Weilanden 9
Wageningen 6708 WG
NL

Scientific

Wageningen Universiteit

Bornse Weilanden 9
Wageningen 6708 WG
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- 20-35 year old male or female
- Body mass index (BMI) 23-27.5 kg/m²
- Suitable veins for blood sampling
- No inhibitory matrix effect in Ara h6 ELISA method
- Able to cycle 1h on ergometer

Exclusion criteria

- History of peanut allergy
- Known symptoms of immune disease, such as diabetes, gastritis, and coeliac disease.
- Pregnant or lactating
- Known symptoms of intestinal disease, such as Crohn*s Disease, ulcerative colitis, and irritable bowel syndrome.
- Smoking
- Use of hard drugs
- Use of specific medicines:
 - o Chronic use of NSAIDs: aspirins, ibuprofen, etc.
 - o Drugs having an effect on gastric and/or intestinal function and motility, including antidepressants.
- Participation in other scientific studies
- Blood donation during the last six weeks before the start and during the study
- Employed at Human Nutrition, Human and Animal Physiology, or Consumer Science and Health(FBR) or performing an internship/thesis at any of these places.

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): 06-06-2016

Enrollment: 10

Type: Actual

Ethics review

Approved WMO

Date: 10-05-2016

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

CCMO

ID

NL57339.081.16