PEANUTS Study

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21995

Source
NTR

Brief title
PEANUTS Study

Health condition

Healthy volunteers, Food allergy, exercise, intestinal permeability, gezonde vrijwilligers, voedselallergie, inspanning, darmdoorlaatbaarheid

Sponsors and support

Primary sponsor: Wageningen University
Source(s) of monetary or material Support: Wageningen University

Intervention

Outcome measures

Primary outcome

The main study parameter is the difference in serum Ara h6 levels over time between a resting and an exercise condition

Secondary outcome

The secondary endpoint is the level of exercise-induced permeability

Other outcomes: Body weight, height, intestinal integrity-related markers, such as I-FABP

Study description

Background summary

In this intervention study 10 healthy participants will ingest 100grams of peanuts and a dual sugar solution during rest (day 1) or with following exercise (day 2, 75%Wmax cycling). A recently developed ELISA method will be used to assess the effect of exercise on circulating levels of Ara h6 after peanut intake and intestinal permeability will be determined.

Study objective

With a recently developed Ara h6 ELISA we would like to show the effect of exercise on circulating Ara h6 after peanut consumption

Study design

Blood is sampled at baseline and at T=30, 60, 90, 120, and 240min after peanut consumption. Levels of Ara h6 will be analysed in serum samples collected at each of the time points with the sandwich ELISA method. Plasma levels of lactulose and rhamnose will be analysed in plasma samples collected at baseline and T=60min after peanut consumption. I-FABP will be measured in plasma samples collected at baseline and at T=30 and T=60 min after peanut consumption.

Intervention

Intake of 100grams of roasted peanuts during 2 test days
Intake of 5g Lactulose and 1gr L-rhamnose during two test days

Blood sampling via venflon cannula at baseline and 30, 60, 90, 120, and 240 min after peanut intake during two test days.

Cycling on ergometer 1hr 75% Wmax during 1 test day

Contacts

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Eligibility criteria

Inclusion criteria

- 20-35 year old males and females

- 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

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2016
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion

Date:	17-05-2016
Application type:	First submission

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
NTR-new	NL5701
NTR-old	NTR5854
Other	NL57339.081.16 : 16/11 METC Wageningen Universiteit

Study results