AAA study

No registrations found.

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

Summary

ID

NL-OMON22155

Source
Nationaal Trial Register

Brief title
AAA study

Health condition

Healthy older subjects (age 65 years or older)

Sponsors and support

Primary sponsor: Nutricia Research B.V.
Source(s) of monetary or material Support: Nutricia Research B.V

Intervention

Outcome measures

Primary outcome

The primary outcome parameter in this study is the time to reach half incremental area under the curve (t½ iAUC) for the sum of all amino acids (total AA) comparing product A to product B.

Secondary outcome

The secondary outcome parameters of this study are:

• The (incremental) maximum amino acid concentration ((i)Cmax), (incremental) area under the concentration curve ((i)AUC) and t½ iAUC comparing all study products for total AA

• Gastric emptying half time (t1/2), Cmax, and time until Cmax is reached (Tmax) and AUC (plasma concentrations of paracetamol) comparing all study products

• Satiety questionnaire

Study description

Background summary

The purpose of the current study is to gain knowledge regarding amino acid bioavailability of different proteins and protein mixes.
Secondly, we aim to study the impact of different proteins on gastric emptying and postprandial fullness and satiety.

This is a randomized, controlled, double-blind, crossover, single-centre study which aims to include 13 healthy older subjects (age 65 years or older) with a minimum of 4 subjects for each sex.

Six different study products will be investigated:
- 4 seperate proteins

- two mixes of these proteins

Study objective

The administered protein mix is related to a faster postprandial amino acid bioavailability compared to a single protein as measured by the t½ of the iAUC.

Study design

Time points of the outcome: V1 (baseline) until V6 (week 6).

Intervention

Duration of intervention: 5 weeks

Intervention group: 5 weeks

Control group: 5 weeks

Contacts

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Eligibility criteria

Inclusion criteria

1. Age 65 years or older

2. BMI from 20 through 30 kg/m2

3. Willingness and ability to comply with the protocol

4. Written informed consent

5. Be judged by the investigator to be in good health

Exclusion criteria

1. Any gastrointestinal (GI) disease or surgery that interferes with GI function

2. Known renal or hepatic failure

3. Known or suspected Diabetes Mellitus (fasting glucose level ¡Ý 7.0 mmol/L)

4. (History of) any cancer with the exception of basal cell carcinoma

5. Fever in the last 7 days prior to Visit 1

6. Haemoglobin in men <7.5 mmol/L and in women <7.0 mmol/L

7. Use of antibiotics, or anticonvulsants, or prokinetics, or antacids or any medication influencing gastric acid production, or oral and systemic use of anticoagulants, or corticosteroids, or laxatives, or growth hormone, or testosterone, or immunosuppressants or insulin within 3 weeks of Visit 1

8. Known severe weight loss (> 3 kg in last 3 months)

9. Participation to a weight loss program

10. Use of protein containing or amino acid containing nutritional supplements within one week of Visit 1

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	03-09-2015
Enrollment:	13
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-09-2015
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	NL5311
NTR-old	NTR5420
Other	: NTS.1.P/H, Nutricia Research B.V.

Study results

Summary results
Not applicable