AAA study

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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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22155

Bron
Nationaal Trial Register

Verkorte titel
AAA study

Aandoening

Healthy older subjects (age 65 years or older)

Ondersteuning

Primaire sponsor: Nutricia Research B.V.
Overige ondersteuning: Nutricia Research B.V

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Duration of intervention: 5 weeks

Intervention group: 5 weeks

Control group: 5 weeks

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	03-09-2015
Aantal proefpersonen:	13
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	02-09-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5311
NTR-old	NTR5420
Ander register	: NTS.1.P/H, Nutricia Research B.V.

Resultaten

Samenvatting resultaten
Not applicable