

Amino acid bioavailability in healthy older adults after bolus intake of high protein oral nutritional supplements

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The amino acid bioavailability of the Test Product is equivalent to Comparator Product 1

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24110

Bron

NTR

Verkorte titel

Pro-Avail

Aandoening

Sarcopenia

Ondersteuning

Primaire sponsor: Nutricia Research – Centre for Specialised Nutrition

Overige ondersteuning: Nutricia Research – Centre for Specialised Nutrition

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome parameter in this study is the Leucine Cmax [$\mu\text{mol/L}$] (product A compared to product B).

Toelichting onderzoek

Achtergrond van het onderzoek

In this study healthy older adults are requested to consume 4 different high-protein nutritional supplements. Each subject will visit the site 4 times and at every visit they will consume 1 of the 4 products after which a series of blood samples will be taken. The blood samples will be analyzed for amino acid bioavailability in the blood up to 4 hours after consumption.

Doel van het onderzoek

The amino acid bioavailability of the Test Product is equivalent to Comparator Product 1

Onderzoeksopzet

Time points of the outcome: every study visit (V1 to V4)

Onderzoeksproduct en/of interventie

Duration of intervention: 4 weeks

Intervention and Control group:

Subjects will be randomised into one of four groups:

Group I: receiving product A, B, C and D in visit 1, 2, 3 and 4 respectively

Group II: receiving product A, B, D and C in visit 1, 2, 3 and 4 respectively

Group III: receiving product B, A, C and D in visit 1, 2, 3 and 4 respectively

Group IV: receiving product B, A, D and C in visit 1, 2, 3 and 4 respectively

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Any gastrointestinal (GI) disease that interferes with GI function
2. Known renal or hepatic failure
3. Known or suspected Diabetes Mellitus (fasting glucose level $\geq$ 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, corticosteroids, growth hormone, testosterone, immunosuppressants or insulin within 3 weeks of Visit 1
8. Known severe weight loss (> 3 kg in last 3 months)
9. Adherence to a weight loss programme
10. Use of protein containing or amino acid containing nutritional supplements within one week of Visit 1
11. Current or recent (within past 3 months) smoking
13. Known allergy to the ingredients of the study products
14. Known galactosaemia
15. Blood donation within 2 months of study entry and during the study

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	02-11-2013
Aantal proefpersonen:	12
Type:	Werkelijke startdatum

Ethische beoordeling

Niet van toepassing

Soort:

Niet van toepassing

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	NL4012
NTR-old	NTR4184
Ander register	Nutricia Research : Spa.1.C.D.34
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A