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

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24110

Source
NTR

Brief title
Pro-Avail

Health condition

Sarcopenia

Sponsors and support

Primary sponsor: Nutricia Research – Centre for Specialised Nutrition
Source(s) of monetary or material Support: Nutricia Research – Centre for Specialised Nutrition

Intervention

Outcome measures

Primary outcome

The primary outcome parameter in this study is the Leucine Cmax [µmol/L] (product A compared to product B).

Secondary outcome

The secondary outcome parameters in this study are comparison of product A and B on:

• Leucine iCmax [µmol/L], iAUC [µmol/L*min] and t½ iAUC [min]

• Essential aminoacids Cmax [µmol/L], iCmax [µmol/L], iAUC [µmol/L*min] and t½ iAUC [min]

• Total sum aminoacids Cmax [µmol/L], iCmax [µmol/L], iAUC [µmol/L*min] and t½ iAUC [min]

• Adverse events and (Gastro-Intestinal) tolerance questionnaire

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

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

Contacts

Public
Nutricia Research
PO Box 80141
3508 TC Utrecht
Carolien Buurman
Uppsalalaan 12

Utrecht
The Netherlands
+31 30 209 50 00
Scientific
Nutricia Research
PO Box 80141
3508 TC Utrecht
Carolien Buurman
Uppsalalaan 12

Utrecht
The Netherlands
+31 30 209 50 00

Eligibility criteria

Inclusion criteria

1. Age 65 years or older

2. BMI from 20 through 30 kg/m2

Exclusion criteria

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 ≥ 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

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-11-2013
Enrollment:	12
Type:	Actual

Ethics review

Not applicable

Application type:	Not applicable

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

Study results

Summary results

N/A