Bioequivalence of oral protein supplements after bolus intake in healthy elderly

Published: 14-12-2015
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The objective of the study is to investigate the bioequivalence of 2 different proteins with regards to bioavailabillity in healthy elderly after one oral bolus intake.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON42515

Source
ToetsingOnline

Brief title
BOSS study

Condition

- Other condition

Synonym
bioequivalence study

Health condition

dit is een bioequivalentie onderzoek

Research involving
Human

Sponsors and support

Primary sponsor: Nutricia Research
Source(s) of monetary or material Support: door de opdrachtgever van het onderzoek.

Intervention

Keyword: Bioequivalence, Healthy elderly, Proteins

Outcome measures

Primary outcome

The primary outcome parameters in this study are Amino Acid AUC [µmol/L*min]

and Cmax [µmol/L]

Secondary outcome

The secondary outcome parameters in this study are:

- Amino Acid Tmax [min] and t* AUC [min]

- Glutamine, EAA and sum AA AUC [µmol/L*min], Cmax [µmol/L], Tmax [min] and t*

AUC [min]

- Safety and GI tolerance parameters

Study description

Background summary

In this study it will be investigated whether equimolar dosages of two proteins will produce bioequivalent amino acid serum levels in healthy older adults. Each subject will come for a screening visit and when eligible for two study visits. At each study visit the subjects will consume one dosage of one of the two study products after which a series of blood samples will be taken.

Study objective

The objective of the study is to investigate the bioequivalence of 2 different proteins with regards to bioavailabillity in healthy elderly after one oral

bolus intake.

Study design

Randomised; double-blind; crossover; single-centre; single-dose

Intervention

After an overnight fast, subjects will ingest one dosage of one of the two study products at each study visit (except during screening).

Study burden and risks

There are no known undesirable effects after the intake of the study products. Expected risks associated with the protocol are minimal. No noticeable effects are expected, except for known side effects of blood collection by a canule. Subjects will receive a reasonable compensation per completed study visit. The compensation includes the costs related to travelling to the study centre.

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age 60 - 80 years (both inclusive)
- BMI from 20 through 30 kg/m2
- Willingness and ability to comply with the protocol
- Written informed consent

Exclusion criteria

- Any gastrointestinal (GI) disease or surgery that interferes with GI function
- Known renal or hepatic failure
- Known or suspected Diabetes Mellitus (fasting glucose level >= 7.0 mmol/L)
- (History of) any cancer with the exception of basal cell carcinoma
- Fever (>38.5 C) in the last 7 days prior to Visit 1

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	04-01-2016
Enrollment:	15

Type:	Anticipated

Ethics review

Approved WMO Date:	14-12-2015
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

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
CCMO	NL55300.072.15