The impact of the macronutrient composition of a nutritional supplement on postprandial skeletal muscle protein synthesis in elderly

Published: 26-08-2011
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Obtain more insight in the preferred macronutrient composition of an oral nutritional supplement.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON39327

Source
ToetsingOnline

Brief title
Pro-Act

Condition

- Other condition
- Muscle disorders

Synonym
age-related loss of muscle mass and muscle function, Sarcopenia

Health condition

Onderzoek vindt plaats in gezonde ouderen en ouderen met sarcopenie

Research involving

Human

Sponsors and support

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

Intervention

Keyword: Elderly, Muscle protein synthesis, Nutritional supplements

Outcome measures

Primary outcome

Mixed muscle protein fractional synthetic rate (FSR) [%/h]

Secondary outcome

Plasma leucine (Leumax [umol/L]; LeuiAUC [umol/(L*min)])

Plasma essential amino acids (EAAmax [umol/L]; EAAiAUC [umol/(L*min)])

Study description

Background summary

Ageing is accompanied by a progressive decline of skeletal muscle mass and function which is named sarcopenia. Loss of muscle function is associated with a decline in mobility and independecy and an increased risk for falling. A possible cause of sarcopenia is a decreased muscle protein synthesis. Specifically for elderly Danone Reseach developed an oral nutritional supplement (ONS) aiming to increase muscle protein synthesis. In this study we will investigate the macronutrient composition of the ONS on skeletal muscle protein synthesis in elderly.
This reserach will give more insight in the preferred macronutrient composition of the ONS.

Study objective

Obtain more insight in the preferred macronutrient composition of an oral nutritional supplement.

Study design

Randomized, controlled, double-blind, parallel-group, single-centre study in healthy elderly
Single-arm study in sarcopenic elderly

Intervention

One single-bolus of one of the three study products

Study burden and risks

For both visits subjects arrive in a fasted state

During the screening visit an oral glucose tolerance test will be performed. The subject has to consume a glucose drink (300 ml) and 1x 10 ml and 4 x 5 ml blood (total volume of 30 mL) is collected. The only risk of blood sampling is a small hematoma.

Functional test are performed to calculate the SPPB score which is used to discriminate between healthy and sarcopenic elderly. Body composition is measured with Dxa. Dxa is a simple, non-invasive procedure which exposes the subjects to a very low dose of radiation (i.e. <1 µSv). No risks associated with this procedure are expected.

All subjects are instructed to refrain from alcohol consumption (24 h) and intense physical activities (72 h) prior to the study visit and keep their normal dietary habits (except from fasting from 22:00 h the evening preceding the study visit). All subjects consume a standardized meal the evening prior to the study visit.

During the study visit we will record medication use during last 3 days prior to study visit. To be able to meaure muscle protein synthesis we will collect 24 x 8 ml blood (total volume of 192 ml) en 4 muscle biopsies. Both blood sampling and muscle biopsy collection can cause a small hematoma. Bleedings and/or infections rarely occur. Muscle biopsy itself can be painfull, but is generally well tolerated. Later on the day of the muscle biopsy and/or in the 2 days after, the muscle can feel a bit sore. This feels like general delayed-onset muscle soreness after exercise and will be completely healed after 2 days.

The subjects will consume 1 single bolus of one the three study products (150 mL). Before and 5 hour after product intake gastrointestinal tolerance will be assessed with an gastrointestinal tolerance questionaire.

Contacts

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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 65 y or older
- Male
- Healthy (n = 45) or sarcopenia (n = 15)
- BMI from 20 through 30 kg/m2
- Written informed consent

Exclusion criteria

- Indications related to inadequate glycemic control
- All co-morbidities interacting with mobility and/or muscle metabolism of the lower limbs
- Any (history of) gastrointestinal disease that interferes with GI function

- Diabetes Mellitus type I or II
- Adherence to a weight loss diet
- Use of protein containing or amino acid containing nutritional supplements within one week of study entry
- Participation in any regular exercise program focusing on improving skeletal muscle mass
- Known allergy to milk and milk products
- Known galactosaemia
- Blood diseases, use of anticoagulants or allergy for lidocaine, because of muscle biopsy collection

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-12-2011
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	26-08-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	27-02-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL36765.068.11