Skeletal muscle protein synthesis in elderly after bolus intake of oral nutritional supplements.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON19903

Source
NTR

Brief title
SPECTATOR

Health condition

Generally healthy elderly

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Muscle protein synthesis rate.

Secondary outcome

Plasma amino acids, insulin, and glucose levels.

Study description

Background summary

Generally healthy elderly volunteers will be asked to participate in this study, which is designed to examine the effect of protein quantity in an oral nutritional supplement on muscle protein synthesis in elderly. Amino acid tracer methodology is applied to measure muscle protein synthesis in the fasted state and after bolus intake of one of two oral nutritional supplements. Muscle biopsies will be taken at two time points to determine the incorporation of the amino acid tracer in the muscle as a measure of protein synthesis. At various time points blood samples will be taken for analyses of amino acid, glucose and insulin levels.

Study objective

A relatively high quantity of dietary protein is needed to stimulate muscle protein synthesis in elderly.

Study design

1. V1: screening visit;

2. V2: intervention visit;

3. FU1: follow-up call (3 days after intervention visit);

4. FU2: follow-up call (5-10 days after intervention visit).

Intervention

1. Duration of intervention: 8 hours;

2. Intervention group: 8 hours;

3. Control group: 8 hours.

Contacts

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Eligibility criteria

Inclusion criteria

1. Generally healthy male or female;

2. Ability to walk, sit down, and stand up independently;

3. Age 60 years or older;

4. BMI between 21 and 30 kg/m2.

Exclusion criteria

1. Co-morbidities:

A. Any (history of) gastrointestinal disease that interferes with GI function;

B. Diagnosed and active treatment of Diabetes Mellitus type I or II;

C. History of congestive heart failure, or recent (6 months) hospitalization for heart disease treatment or management (e.g. PTCA, stent, surgery), or myocardial infarction in the past year.

2. Infection or fever in the last 7 days;

3. Medication:

A. Use of antibiotics within 3 weeks prior to the study visit;

B. Current use of corticosteroids, growth hormone, or testosterone.

4. Dietary or life style characteristics:

A. Adherence to a weight loss diet;

B. Use of protein containing or amino acid containing nutritional supplements within one week of study entry;

C. Current participation in muscle strengthening program.

5. Contraindications to biopsy procedure:

A. Platelet count (PLT) < 100,000;

B. History of hypo- or hyper-coagulation disorders including use of a coumarin derivative, history of deep venous thrombosis (DVT), or pulmonary embolism (PE) at any point in lifetime;

C. Currently taking anti-thrombotics and cannot stop for 7 days (i.e. medical indication);

D. Allergy to local anaesthetic.

6. Blood hemoglobin < 9.0 g/dL.

Study design

Design

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

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	19-05-2009
Enrollment:	20
Type:	Actual

Ethics review

Positive opinion Date:	19-05-2009
Application type:	First submission

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	NL1713
NTR-old	NTR1823
Other	Danone Research – Centre for Specialised Nutrition : SPA.1.C/A
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A