

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

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON19903

Bron

NTR

Verkorte titel

SPECTATOR

Aandoening

Generally healthy elderly

Ondersteuning

Primaire sponsor: Danone Research – Centre for Specialised Nutrition

Overige ondersteuning: Danone Research – Centre for Specialised Nutrition

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Muscle protein synthesis rate.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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).

Onderzoeksproduct en/of interventie

1. Duration of intervention: 8 hours;
2. Intervention group: 8 hours;
3. Control group: 8 hours.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestopt

(Verwachte) startdatum: 19-05-2009
Aantal proefpersonen: 20
Type: Werkelijke startdatum

Ethische beoordeling

Positief advies
Datum: 19-05-2009
Soort: Eerste indiening

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

Resultaten

Samenvatting resultaten

N/A