Spierbehoud studie.

Gepubliceerd: 11-02-2011 Laatst bijgewerkt: 18-08-2022

A protein supplement has a positive effect on muscle mass, muscle strength and physical functioning during a weight loss trial in overweight elderly.

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

Samenvatting

ID

NL-OMON24688

Bron
Nationaal Trial Register

Verkorte titel
Muscle preservation study

Aandoening

(Abdominal) obesity, adiposity
(Abdominale) obesitas, adipositas

Ondersteuning

Primaire sponsor: dr.ir. Peter J.M. Weijs
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Danone Research B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Change in appendicular muscle mass (DXA).

Toelichting onderzoek

Achtergrond van het onderzoek

To investigate the superiority of a specialised Oral Nutritional Supplement (ONS) vs a control product on muscle mass, body composition, muscle strength, physical functioning and QoL in overweight elderly (55-85y) during a 13 week weight loss period.

Doel van het onderzoek

A protein supplement has a positive effect on muscle mass, muscle strength and physical functioning during a weight loss trial in overweight elderly.

Onderzoeksopzet

1. Baseline;

2. After 7 weeks;

3. After 13 weeks.

Onderzoeksproduct en/of interventie

Duration of intervention: 13 weeks.

1. Intervention group: All participants in the intervention group will receive 10 servings a week of the Active study product, which has a high protein content;

2. Control group: All participants in the control group will receive 10 servings a week of the (isocaloric) Control product.

Both products consist of about 40 grams of powder which has to be dissolved in 125 ml of water and are available in two flavors: vanilla and strawberry.

During the intervention period, subjects consume one serving a day, and on training days one extra (3 days per week).

Both groups will be enrolled in a hypo-caloric weight loss diet and participate in a resistance exercise program comprising 3 supervised group sessions per week at the study centre.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age between 55 and 85 years;

2. BMI > 30 or BMI > 28 + waist circumference > 88 cm (women), > 102 cm (men);

3. Willingness and ability to comply with the study protocol, including:

A. Following dietary advice;

B. Participation in study visits;

C. Taking the study products every day;

D. Ability to comply with the complete study protocol;

E. Ability to understand and fill out questionnaires.

4. The physiotherapist’s view is that the subject is physically fit;

5. Safe to participate in the resistance exercise protocol.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Any malignant disease during the last five years except for adequately treated prostate cancer without evidence of metastases, localized bladder cancer, cervical carcinoma in situ, breast cancer in situ or non-melanoma skin cancer;

2. Previously known:

A. Kidney failure (previous glomerular filtration rate <30 ml/min);

B. Liver failure;

C. Anaemia (Haemoglobin in men <6.5 mmol/l and women <6.0 mmol/l);

D. (Chronic) inflammatory status.

3. Medication:

A. Corticosteroids for systemic use;

B. Immunosuppressants;

C. Insulin.

4. Dietary or lifestyle characteristics:

A. Participation in a weight loss diet three months before starting and during the study;

B. Use of protein-containing or amino acid-containing nutritional supplements three months before starting and
during the study;

C. Participation in a resistance exercise program three months before starting and during the study;

D. Current alcohol or drug abuse in opinion of the sponsor-investigator.

5. Indications related to interaction with the study product:

A. More than 10 Ig (400 IU) of daily Vitamin D intake from medical sources;

B. More than 500 mg of daily calcium intake from medical sources;

C. Known allergy to milk and milk products;

D. Known galactosaemia.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	16-02-2011
Aantal proefpersonen:	80
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	11-02-2011
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	NL2623
NTR-old	NTR2751
Ander register	ABR / METc VUMc : 33971 / 2010/280;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

Verreijen AM, Verlaan S, Engberink MF, Swinkels S, de Vogel-van den Bosch J, Weijs PJ. A high whey protein-, leucine-, and vitamin D-enriched supplement preserves muscle mass during intentional weight loss in obese older adults: a double-blind randomized controlled trial. Am J Clin Nutr. 2015 Feb;101(2):279-86.