Spierbehoud studie.

No registrations found.

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

Summary

ID

NL-OMON24688

Source
NTR

Brief title
Muscle preservation study

Health condition

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

Sponsors and support

Primary sponsor: dr.ir. Peter J.M. Weijs
VU Medical Centre
De Boelelaan 1117
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Source(s) of monetary or material Support: University of Applied Science, Amsterdam (Hogeschool van Amsterdam)
Danone Research B.V.

Intervention

Outcome measures

Primary outcome

Change in appendicular muscle mass (DXA).

Secondary outcome

1. Body composition (BodPod, BIA);

2. Muscle strength (hand-grip, leg-extension);

3. physical functioning (chair stand, gait speed, 400m walking test);

4. Quality of Life (RAND-36 questionaire).

Study description

Background summary

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.

Study objective

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

Study design

1. Baseline;

2. After 7 weeks;

3. After 13 weeks.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-02-2011
Enrollment:	80

Type:	Actual

Ethics review

Positive opinion

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

Study results

Summary results

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.