Effect of nutritional supplementation on physical performance in elderly.

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Dietary management with the medical food under study has a positive effect on muscle strength and physical functioning in elderly.

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

Samenvatting

ID

NL-OMON24840

Bron
Nationaal Trial Register

Verkorte titel
PROVIDE

Aandoening

Sarcopenia

Ondersteuning

Primaire sponsor: Danone Research - Centre for Specialized Nutrition
Overige ondersteuning: Danone Research - Centre for Specialized Nutrition

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Muscle strength (hand dynamometry) during 13 weeks of intervention;
2. Physical Performance (test battery) during 13 weeks of intervention.

Toelichting onderzoek

Achtergrond van het onderzoek

To investigate the superiority of a specialised Oral Nutritional Supplement (ONS) on muscle strength, physical functioning, QoL, and ADL in elderly vs a control product.

Doel van het onderzoek

Dietary management with the medical food under study has a positive effect on muscle strength and physical functioning in elderly.

Onderzoeksopzet

0, 7, 13, and 26 weeks.

Onderzoeksproduct en/of interventie

Duration of intervention: 13 weeks with an optional extension period of 13 weeks.

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

2. Control group: All participants in the control group will receive daily two servings 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 two servings per day. In the facultative extension period subjects are randomized into a group consuming one serving and a group consuming two servings per day.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age 65 years or older;

2. Performance Score (SPPB) from 4 through 9;

3. Class I or II sarcopenia, measured with bioelectrical impedance assessment (BIA);

4. BMI 20 - 30 kg/m2;

5. Informed consent;

6. Willingness and ability to comply with the 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. Known kidney failure (previous glomerular filtration rate <30 ml/min);

3. Known liver failure;

4. Moderately severe and severe anaemia (Haemoglobin in men <6.5 mmol/l and women <6.0 mmol/l);

5. (Chronic) inflammatory status (CRP level >10 mg/L);

6. Psychiatric disease, i.e.:

A. Depression: Geriatric Depression Scale (15 items) >8;

B. Schizophrenia symptomatic disease;

C. Dementia: Mini Mental State Examination <25.
7. Medication: Antidepressants, Neuroleptics, Corticosteroids for systemic use, immunosuppressants, insulin;

8. Malnutrition:

A. Known severe weight loss (>3 kg in the last 3 months);

B. BMI <20 kg/m2;

C. Severe loss of appetite.
9. Severe impairments of hand-function that will obstruct reliable grip strength measurements (e.g. rheumatoid arthritis);

10. Dietary or life style characteristics:

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

B. Adherence to a high energy or high protein diet three months before starting and during the study;

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

11. Participation in a muscle strengthening program three months before starting and during the study;

12. Current alcohol or drug abuse in opinion of the investigator;

13. Indications related to the study product:

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

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

14. Known allergy to milk and milk products;

15. Known galactosaemia;

16. Investigator's uncertainty about the willingness or ability of the subject to comply with the protocol requirements;

17. Participation in any other study involving investigational or marketed products concomitantly or within four weeks prior to entry into the study.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-06-2010
Aantal proefpersonen:	300
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	18-05-2010
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	NL2205
NTR-old	NTR2329
Ander register	Danone Research Centre for specialised nutrition : Protocol Spa.1.C/D
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A