Effect of nutritional supplementation on physical performance in elderly.

No registrations found.

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

Summary

ID

NL-OMON24840

Source
NTR

Brief title
PROVIDE

Health condition

Sarcopenia

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

1. Muscle strength (hand dynamometry) during 13 weeks of intervention;

2. Physical Performance (test battery) during 13 weeks of intervention.

Secondary outcome

1. Physical activity (Questionnaire);

2. Appendicular muscle mass (DXA and BIA);

3. Health related quality of life (Questionnaire);

4. Independence of ADL (Questionnaire).

Study description

Background summary

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.

Study objective

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

Study design

0, 7, 13, and 26 weeks.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

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. 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.

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):	01-06-2010
Enrollment:	300
Type:	Actual

Ethics review

Positive opinion

Date:	18-05-2010

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	NL2205
NTR-old	NTR2329
Other	Danone Research Centre for specialised nutrition : Protocol Spa.1.C/D
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A