# An exploratory study into the acute and long-term effects of high-protein supplementation on postprandial muscle protein metabolism in healthy elderly.

No registrations found.

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

## Summary

### ID

NL-OMON27334

**Source**
Nationaal Trial Register

**Brief title**
Pro-Motion

**Health condition**

Sarcopenia

### Sponsors and support

**Primary sponsor:** Danone Research – Centre for Specialised Nutrition
**Source(s) of monetary or material Support:** Danone Research – Centre for Specialised Nutrition

### Intervention

### Outcome measures

**Primary outcome**

Mixed muscle protein fractional synthetic rate (FSR) [%/h].

### Secondary outcome

1. Rate of phenylalanine uptake by the forearm [µmol/100ml.min];

2. Rate of phenylalanine release by the forearm [µmol/100ml.min];

3. Forearm phenylalanine net balance [µmol/100ml.min].

## Study description

### Background summary

To investigate the effect of a protein-rich nutritional supplement on parameters for muscle metabolism.

### Study objective

The protein-rich nutritional supplement increases muscle protein synthesis.

### Study design

0 and 6 weeks.

### Intervention

Duration of intervention: 6 weeks.

1. Intervention group: Protein-rich nutritional supplement. One daily serving (200mL) taken before breakfast;

2. Control group: Placebo product. One daily serving (200mL) taken before breakfast.

## Contacts

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# Eligibility criteria

## Inclusion criteria

1. Age 65 y or older;

2. Male;

3. BMI from 20 through 30 kg/m2;

4. Willingness and ability to comply with the protocol;

5. Written informed consent.

## Exclusion criteria

1. Prior or current participation in any other clinical study using phenylalanine stable isotopes;

2. Indications related to inadequate glycemic control;

3. Co-morbidities:

A. All co-morbidities interacting with mobility and/or muscle metabolism of the lower limbs and hands;

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

C. Any (history of) gastrointestinal (GI) disease that interferes with GI function;

D. Known kidney failure;

E. Known liver failure;

F. Moderately severe and severe anaemia;

G. Diabetes Mellitus type I or II;

H. (Chronic) inflammatory status;

I. Any known food allergy to the ingredients of the breakfast consumed during study visits;

J. Dementia: Mini Mental State Examination <25.

4. Medication:

A. Use of oral or systemic antibiotics within 3 weeks prior to study visit;

B. Current oral or systemic use of corticosteroids, testosterone, growth hormone, immunosuppressants, tricyclics, opiates, barbiturates or insulin.

5. Malnutrition:

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

B. Severe loss of appetite.

6. Dietary or life style characteristics:

A. Adherence to a weight loss diet three months before 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 within one week of study entry and during the study;

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

E. Current or recent (within past 3 months) smoking;

F. Current alcohol or drug abuse in opinion of the investigator.

7. Indications related to the study product:

A. A cumulative monthly dose of more than 140 ìg (5600 IU) of vitamin D supplementation administrated according to a weekly or monthly regimen during the last three months;

B. More than 5 ìg (200 IU) of daily vitamin D intake from medical sources (including food supplements and vitamin supplements);

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

D. Known allergy to milk and milk products;

E. Known galactosaemia.

8. Contraindications related to muscle biopsy procedure:

A. Blood diseases;

B. Use of anticoagulants;

C. Allergy for lidocaine;

D. Prostate hypertrophy (Prostate specific antigen > 4 ìg/L) ;

E. Glaucoma.

9. Blood donation within 2 months of study entry, during the study and 1 month after study completion;

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

11. Participation in any other study involving investigational or marketed products concomitantly or within 4 weeks prior to entry into the study.

# Study design

## Design

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|---|---|
| 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): | 01-09-2012 |
| Enrollment: | 24 |
| Type: | Actual |

## Ethics review

Positive opinion

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|---|---|
| Date: | 11-06-2012 |
| 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 | NL3324 |
| NTR-old | NTR3471 |
| Other | Danone Research / CPP : Spa.1.C/G / 2011-A01399-32; |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

## Study results

**Summary results**

Audrey Chanet, Sjors Verlaan, Jérôme Salles, Christophe Giraudet, Véronique Patrac, Véronique Pidou, Corinne Pouyet, Nordine Hafnaoui, Adeline Blot, Noël Cano, Nicolas Farigon, Anke Bongers, Marion Jourdan, Yvette Luiking, Stéphane Walrand, Yves Boirie; Supplementing Breakfast with a Vitamin D and Leucine–Enriched Whey Protein Medical Nutrition Drink Enhances Postprandial Muscle Protein Synthesis and Muscle Mass in Healthy Older Men, The Journal of Nutrition, Volume 147, Issue 12, 1 December 2017, Pages 2262–2271, https://doi.org/10.3945/jn.117.252510