# The impact of dietary protein supplementation and age on muscle mass loss during short term one-legged knee immobilization

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To investigate whether elderly individuals lose muscle mass at a greater rate than young individuals during 5 days of one legged knee immobilization, and whether dietary protein supplementation can alleviate such muscle loss in the elderly.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON37842

**Source**
ToetsingOnline

**Brief title**
IM-PRO

### Condition

- Other condition
- Protein and amino acid metabolism disorders NEC
- Muscle disorders

**Synonym**
disuse atrophy

**Health condition**

muscle metabolism

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Universiteit Maastricht
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Age, Immobilization, Protein supplementation, Skeletal muscle

## Outcome measures

### Primary outcome

Quadriceps cross sectional area (CSA).

### Secondary outcome

Leg lean mass, type I and II muscle fiber CSA and satellite cell content,

muscle strength, mRNA and protein expression of anabolic signaling proteins.

# Study description

### Background summary

Situations such as injury or illness can necessitate a period of muscle disuse (limb immobilization or bed-rest) in otherwise healthy individuals. Even brief periods of such muscle disuse lead to a rapid loss of muscle mass and, consequently, functional strength. This is of major relevance to elderly individuals who already have a compromised functional capacity. However, it remains unknown whether elderly individuals are more susceptible to muscle loss during disuse compared to the young. Furthermore, whether muscle loss can be alleviated during disuse by increasing dietary protein intake remains equivocal.

### Study objective

To investigate whether elderly individuals lose muscle mass at a greater rate than young individuals during 5 days of one legged knee immobilization, and whether dietary protein supplementation can alleviate such muscle loss in the

elderly.

### Study design

Randomized, parallel (three groups) study design.

### Intervention

Five days of one-legged knee immobilization in young individuals (YNG group), and five days of one-legged knee immobilization in elderly individuals with (OLD-PRO) or without (OLD-CON) twice daily dietary protein supplementation.

### Study burden and risks

The risks involved in participating in this experiment are minimal. Muscle biopsies will be taken through a small (5 mm) incision, following local anesthetics of the skin and muscle fascia, and will heal completely. Muscle biopsies will only be obtained by an experienced physician. Five days of limb immobilization via a full leg cast will impair subject*s mobility for this period. However, to minimize any risk of injury subjects will not be allowed to drive a vehicle or ride a bicycle and will have daily contact with the investigators. The 5 day immobilization period will lead to a loss of muscle mass and strength. However, the expected loss of muscle mass and strength following immobilization will be rapidly (<2 weeks) regained due to the inclusion of only healthy volunteers.

## Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

Male
Aged from 18-35 years and from 65-75 years
18.5 < BMI < 30 kg/m2

## Exclusion criteria

Smoking
Performing regular resistance training in the previous 6 months
Hypertension (according to WHO criteria) and/or cardiovascular disease
Any back/leg/knee/shoulder complaints which may interfere with the use of crutches
Systemic use of antibiotics within 3 weeks prior to the study visit
Current systemic use of corticosteroids, growth hormone, testosterone, immunosuppressants or insulin
Type 2 diabetes mellitus
Any family history of thrombosis
All co-morbidities interacting with mobility and muscle metabolism of the lower limbs (e.g. arthritis, spasticity/rigidity, all neurological disorders and paralysis)
Myocardial infarction within the last 3 years
Use of anti-coagulants

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |

**Primary purpose:** Basic science

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 22-05-2012 |
| Enrollment: | 60 |
| Type: | Actual |

# Ethics review

Approved WMO

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|---|---|
| Date: | 27-04-2012 |
| Application type: | First submission |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |

# 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 |
| --- | --- |
| CCMO | NL39878.068.12 |