# Pre-operative protein feeding to stimulate muscle and bone synthesis in older patients undergoing elective hip surgery

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

# Summary

### ID

NL-OMON27141

**Source** Nationaal Trial Register

Brief title Pre-HIP

#### **Health condition**

Sarcopenia, Pre-operative feeding, Muscle disuse atrophy, Elective hip surgery

### **Sponsors and support**

**Primary sponsor:** Maastricht University Medical Center (MUMC+), TI Food & Nutrition **Source(s) of monetary or material Support:** TI Food and Nutrition

### Intervention

#### **Outcome measures**

#### **Primary outcome**

The primary outcome is muscle and bone protein synthesis expressed as fractional synthesis

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rates (FSR, %/h). Muscle and bone-protein bound, muscle and bone-tissue free and plasma amino acid enrichments will be measured to calculate precusor and product enrichments.

#### Secondary outcome

- Total plasma amino acids
- Plasma glucose
- Plasma insulin
- Plasma amino acid enrichments
- GI tolerance
- Liver, kidney and muscle function

# **Study description**

#### **Background summary**

Aging is associated with a gradual loss of skeletal muscle mass and function, termed sarcopenia. Periods of hospitalization and immobilization can increase the rate of muscle loss. Dietary protein supplementation represents an effective strategy to preserve skeletal muscle mass by stimulating muscle protein synthesis. In line, we propose that pre-operative feeding forms an effective nutritional strategy to stimulate muscle protein synthesis during surgery and, as such, improves subsequent recovery.

#### **Study objective**

Protein feeding prior to surgery enhances muscle and bone protein synthesis rates in the post-prandial period when compared to the non-feeding condition in older patients undergoing total hip arthroplasty.

#### Study design

Timepoints in this study:

1. Evening prior to surgery: Informed consent, DEXA-scan, questionnaires, placement of naso-duodenal tube;

2. Morning prior to surgery: placement of two intravenous catheters, infusion of stable isotope amino acids, administration of protein-rich supplement, blood draws every hour, questionnaire.

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3. Surgery: muscle and bone collection, blood draws every hour

#### Intervention

1. This study will be conducted in older patients attending the department of Orthopedics with a scheduled total hip arthroplasty.

2. Subjects are randomized into a feeding and non-feeding group (no intervention).

3. Continuous stable isotope infusions will be applied in both groups to measure muscle and bone protein synthesis rates.

4. Subjects in the feeding group will receive a protein-rich supplement via enteral administration prior to surgery.

5. During the pre- and perioperative period, 6 venous bloodsamples, a muscle biopsy and bone sample will be taken to measure turnover rates.

# Contacts

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# **Eligibility criteria**

## **Inclusion criteria**

1. Patients scheduled for total hip arthroplasty;

2. 60-85 years;

3. BMI: 18.5-35 kg/m^2;

4. Functioning gastrointestinal tract, eligible for tube feeding via an intestinal tube.

### **Exclusion criteria**

1. Co-morbidities and neuromuscular disorders of the lower limbs severely interacting with mobility;

2. Co-morbidities severely interacting with muscle metabolism of the lower limbs;

3. Known renal malfunction (Known renal malfunction without documented approval from nephrologist);

- 4. Known allergy to milk, milk products and soy;
- 5. Known galactosaemia;
- 6. Known gastrointestinal medical history.

# Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-08-2015
Enrollment:	24
Туре:	Anticipated

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# **Ethics review**

Positive opinion Date: Application type:

08-07-2015 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	NL5154
NTR-old	NTR5294
Other	: METC 15-30-19

# **Study results**

# Summary results N/A