

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

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Muscle disorders
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON43923

### Source

ToetsingOnline

### Brief title

Pre-operative protein feeding

### Condition

- Muscle disorders

### Synonym

muscle atrophy, muscle wasting, Sarcopenia

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universiteit Maastricht

**Source(s) of monetary or material Support:** Ministerie van OC&W, TI Food and Nutrition

## Intervention

**Keyword:** Bone synthesis, Elderly, Muscle protein synthesis, Protein

## Outcome measures

### Primary outcome

- Muscle protein-bound L-[ring-13C6]-phenylalanine enrichments (expressed as MPE)
- Bone protein-bound L-[ring-13C6]-phenylalanine enrichments (expressed as MPE)
- Muscle tissue-free L-[ring-13C6]-phenylalanine enrichments (expressed as MPE)
- Bone tissue-free L-[ring-13C6]-phenylalanine enrichments (expressed as MPE)
- Plasma L-[ring-13C6]-phenylalanine enrichments (expressed as MPE)

### Secondary outcome

Secondary endpoints will be plasma amino acid concentrations (i.e. total and essential amino acids, leucine, phenylalanine and albumin), and glucose, and insulin concentrations during surgery.

## 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. Stimulating muscle protein synthesis, may prevent muscle atrophy, attenuate a decline in mitochondrial function, and support tissue repair. Moreover, bone turnover might be sensitive to nutrients; therefore protein ingestion prior to surgery may benefit skeletal

muscle and bone health following major surgery. We hypothesize that providing dietary protein prior to surgery stimulates muscle and bone protein synthesis, and as such, represents a feasible nutritional strategy to attenuate the loss of skeletal muscle mass and improve recovery in older patients undergoing a total hip replacement surgery.

## **Study objective**

The primary objective is to test the hypothesis that a protein-rich nutritional supplement (containing 45 g of dietary protein) prior to surgery acutely increases skeletal muscle and bone protein synthesis rates in older patients undergoing a hip arthroplasty during operative treatment.

## **Study design**

Randomized controlled, single-center, intervention study.

## **Intervention**

Subjects will receive 600 mL of a protein-rich enteral feed (nutritional supplement: Nutrison Advanced Protison, containing 7.5 g protein, 15.4 g carbohydrates, and 3.7 g fat per 100 mL) prior to hip arthroplasty (PRO) or no nutritional intervention (PLA). Since aspiration of gastric contents can lead to serious complications, nutrition will be applied via naso-duodenal tube feeding, in order to bypass the stomach and directly deliver amino acids in the small intestine.

## **Study burden and risks**

The burden and risks associated with participation are small. Muscle and bone samples will be taken in the operating room during the surgery, when the patient is anaesthetized, which will therefore be a painless procedure. As a result of the muscle biopsy, patients may experience some minor discomfort for maximally up to 24 h after the procedure, characterized as a feeling that is comparable to muscle soreness or the pain after bumping into a table. The incision made for obtaining the muscle biopsy will heal completely. Blood samples will be drawn prior to surgery (4 blood samples of 8 mL). An intravenous cannula will be placed prior to surgery. Insertion of the catheters in a vein is comparable to a normal blood draw with the risk of a small local haematoma. Nutritional intervention might benefit the recovery of individuals in the PRO group after surgery. Placement of a naso-duodenal tube however might give some discomfort and possibly complications as nose bleeds, sinusitis and a sore throat. The test beverages are commercially available for clinical use and are therefore safe for human consumption. The labelled amino acid tracers applied in this experiment are not radioactive and are completely safe.

## Contacts

### Public

Universiteit Maastricht

Universiteitssingel 50  
Maastricht 6229 ER  
NL

### Scientific

Universiteit Maastricht

Universiteitssingel 50  
Maastricht 6229 ER  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Osteoarthritis of the hip, planned for operative treatment

Age 40-85 yr

BMI 18.5 - 35

MNA-score >17

### Exclusion criteria

- Co-morbidities and neuromuscular disorders of the lower limbs severely interacting with mobility
- Co-morbidities severely interacting with muscle metabolism of the lower limbs
- Gastrointestinal disease

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- Known renal malfunction without documented approval from nephrologist)
- Known allergy to milk, milk products and soy
- Known galactosaemia

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Basic science

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	12-01-2016
Enrollment:	32
Type:	Actual

## Ethics review

Approved WMO	
Date:	24-06-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	
Date:	01-10-2015
Application type:	Amendment
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	NL52847.068.15