Skeletal muscle atrophy in elderly hip surgery patients during hospital admission.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23029

Source
NTR

Brief title
Muscle loss after hip surgery

Health condition

Hip fracture, elective hip surgery, muscle loss, falls and fractures

Sponsors and support

Primary sponsor: Maastricht University Medical Centre
TIFN: Top Institute for Food and Nutrition
Source(s) of monetary or material Support: European Union

Intervention

Outcome measures

Primary outcome

The primary parameters in this study are the cross-sectional area of the quadriceps muscle and the cross-sectional area of type I and type II skeletal muscle fibers.

Secondary outcome

Secondary outcome parameters in this study are satellite cell content in the type I en type II skeletal muscle fibers, functional outcome 6 months after hospital admission (determined by the use of the PASE score and Hip Fracture Functional Recovery Scale), and quality of life (SF-36) 6 months after admission.

Baseline subject characteristics will be obtained, including height, bodyweight, medical history, use of medication, mental status (determined by the MMSE), smoking, use of alcohol, use of drugs, level of habitual physical activity (determined by PASE, Hip Fracture Recovery Scale), and quality of life (SF-36). The nutritional status of the patients will also be measured, using the MNA and MUST questionnaires. Lean body mass and bone mineral density will be determined by DEXA. In addition, blood samples will be analyzed for HbA1c, CRP, calcidiol, and TNF-á.

Study description

Background summary

Aging is associated with gradual loss of skeletal muscle mass and function, termed sarcopenia. Loss of muscle mass may result in impaired mobility and an increased risk of falling, thereby leading to fractures of the hip. Hip fracture is a common cause of morbidity and mortality in the elderly. Hospitalization and immobilization increase the rate of muscle loss. In order to maintain muscle mass, nutritional interventions have proven to be an effective manner to reduce the loss of muscle mass by stimulating muscle protein synthesis. However, it is unclear to what extend loss of muscle mass occurs during hospitalization. In addition, the role of nutritional support with high protein drinks after surgery will be performed to overcome the loss of muscle mass.

The primary objective is to study the course of muscle (fiber) atrophy in elderly females with a fall-related hip fracture or elective hip surgery and the influence of additional nutritional support during hospital admission.

Secondary objectives of this study are to study the relation between muscle atrophy and functional outcome in elderly female patients with a fall-related hip fracture; to study the relation between muscle atrophy and the development of complications in elderly female patients with a fall-related hip fracture; and to compare muscle mass and fiber characteristics, and the changes in these parameters during hospitalization, between elderly female patients with a fall-related hip fracture and elective hip surgery.

Study objective

Muscle mass and muscle fiber size will decline in elderly female patients with a fall-related hip fracture and elective hip surgery will increase during hospital admission. The extent of

muscle (fiber) atrophy will be a prognostic factor for functional outcome and the development of complications. A nutritional intervention will attenuate the extent of muscle fiber atrophy during hospital admission.

Study design

Timepoints in this study:

1. Before operation: Informed consent, CT-scan, and questionnaires;

2. Operation (t=0): Muscle biopsy;

3. After operation (t=0 1/m 10): Blood draws, nutriotional intervention;

4. After operation (t=10): Second biopsy, second CT-scan, DEXA scan;

5. After operation (t= 6 months): Questionnaires.

Intervention

Hospitalization of elderly women might be considered an important cause of loss of muscle mass and quality of life. However, the exact course of muscle mass loss during hospitalization remains to be determined. Furthermore, nutritional supplementation represents a potential intervention when targeting hospitalization induced disuse atrophy, especially in hip fracture patients who often appear malnourished. Therefore, the present study will determine changes in muscle mass and muscle fiber characteristics during hospitalization in elderly women undergoing hip surgery (either elective hip replacement or as surgical treatment for a sustained hip fracture). In addition, the potential beneficial effects of a protein-rich nutritional supplement will be evaluated, specifically in the group of hip fracture patients.

This study will be conducted in all elderly female patients attending the department of General Surgery with a fall-related hip fracture or elective hip surgery.The following interventions will take place:

1. Inclusion is done at the Emergency department. After inclusion, the first single slice CT-scan is made of the non-fractured leg;

2. During the operative treatment of the hip, the first muscle biopsy will be obtained from the vastus lateralis muscle of the treated leg;

3. One blood sample (8 ml) will be collected during the primary surgical procedure and every 2 days during hospital admission, for a maximum of 10 days;

4. For fracture patients randomly allocated to the group receiving nutritional intervention, supplementation of the nutritional supplement will start within 12 hours after surgery. Patients will receive one serving of the nutritional supplement during breakfast (8.00 am), and one serving prior to sleeping (10.00 pm);

5. functional parameters and quality of life of the pre-admission period are registered using the following questionnaires: SF-36, Groningen activity restriction scale, and Hip Fracture Functional Recovery Score;

6. A second muscle biopsy is taken prior to hospital discharge or at a maximum of 10 days after the operation took place;

7. A second single slice CT-scan is performed prior to discharge or at a maximum of 10 days after surgery;

8. A DEXA-scan is made at the day of discharge. This is used to assess the body composition of the patient.

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Eligibility criteria

Inclusion criteria

1. Hip fracture or osteoarthritis of the hip;

2. >65 years of age;

3. Operative treatment.

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. A life-expectancy of less than 6 months.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2013
Enrollment:	60
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL3544
NTR-old	NTR3773
Other	METC : 12-3-059
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A