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

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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...

Ethische beoordeling Niet van toepassing

Status Werving nog niet gestart

Type aandoening -

Onderzoekstype Interventie onderzoek

Samenvatting

ID

NL-OMON23029

Bron

NTR

Verkorte titel

Muscle loss after hip surgery

Aandoening

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

Ondersteuning

Primaire sponsor: Maastricht University Medical Centre

TIFN: Top Institute for Food and Nutrition

Overige ondersteuning: European Union

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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
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after surgery;

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 1. Hip fracture or osteoarthritis of the hip;
- 2. >65 years of age;
- 3. Operative treatment.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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;
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- 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.

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel: Parallel

Toewijzing: Gerandomiseerd

Blindering: Open / niet geblindeerd

Controle: N.v.t. / onbekend

Deelname

Nederland

Status: Werving nog niet gestart

(Verwachte) startdatum: 01-02-2013

Aantal proefpersonen: 60

Type: Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register ID

NTR-new NL3544 NTR-old NTR3773

Ander register METC: 12-3-059

ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A