

FEmoral BOne fracture study

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We expect the protein synthesis rate in (avascular) femoral bone proximal to the fracture to be lower when compared to healthy femoral bone.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20798

Bron

NTR

Verkorte titel

FEBO

Aandoening

Hip fracture

Ondersteuning

Primaire sponsor: Maastricht University

Overige ondersteuning: Maastricht University

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Bone protein synthesis rates in the femoral shaft and femoral head tissue, expressed in FSR (%/h)

Toelichting onderzoek

Achtergrond van het onderzoek

Skeletal muscle plasticity is defined by a dynamic balance between protein synthesis and protein breakdown rates. Recently, we have shown basal protein synthesis rates in various musculoskeletal tissues of the knee joint, including bone, cartilage, and tendon tissue. Interestingly, most of these tissues possess protein synthesis rates within the same range of skeletal muscle protein synthesis rates. However, it is not known whether the protein synthesis rates of bone tissue change after a traumatic event (i.e. bone fracture). In older adults, hip fractures are one of the most common fractures that require surgical intervention. After a hip fracture, the vitality of the femoral head is often reduced. It is not known whether osteonecrosis of the femoral head happens due to reduced protein synthesis or extensive breakdown. Therefore, this project will apply the stable isotope methodology to measure tissue-specific protein synthesis rates in fractured femoral bone.

Doel van het onderzoek

We expect the protein synthesis rate in (avascular) femoral bone proximal to the fracture to be lower when compared to healthy femoral bone.

Onderzoeksopzet

2.5h before start of surgery until the end of the surgical procedures.

Onderzoeksproduct en/of interventie

None

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 1) Written informed consent;
- 2) Recent (<24 h before admission to the hospital) femoral bone fracture requiring hip replacement surgery;
- 3) Admitted to MUMC+ to receive a femoral head-neck prosthesis or total hip replacement.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 1) Physical restlessness due to delirium;
- 2) Rheumatoid arthritis;
- 3) Chemotherapy or radiotherapy;
- 4) (Multiple) Myeloma or other primary cancer tumor with possible bone metastasis;)
- 5) Collagen disorders, e.g. Marfan and Ehler-Danlos;
- 6) Any other medical condition that may interfere with the safety of the subjects or the outcome parameters, in the investigators judgement;
- 7) Investigator's uncertainty about the willingness or ability of the subject to comply with the protocol instructions;
- 8) Participation in any other studies involving investigational or marketed products concomitantly to entry into the study.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-12-2020
Aantal proefpersonen:	10
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	04-11-2020
Soort:	Eerste indiening

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	NL9036
Ander register	METC AzM/UM : METC 20-082

Resultaten

Samenvatting resultaten

The results of this investigation will be published in a high-impact, scientific journal, regardless of the outcome of this study.