FEmoral BOne fracture study

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20798

Source NTR

Brief title FEBO

Health condition

Hip fracture

Sponsors and support

Primary sponsor: Maastricht University Source(s) of monetary or material Support: Maastricht University

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

The secondary outcome parameters are tissue-specific protein synthesis rates in femoral bone, femoral head cartilage, hip synovium, and m. gluteus maximus, expressed in FSR

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Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

None

Contacts

Public

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Scientific

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Research in Metabolism / Department of Human Biology Floris Hendriks

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Observational non invasive
Other
Non controlled trial
Open (masking not used)
N/A , unknown

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2020
Enrollment:	10
Туре:	Actual

IPD sharing statement

Plan to share IPD: Undecided

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Fthics	review

Positive opinion	
Date:	04-11-2020
Application type:	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	NL9036
Other	METC AzM/UM : METC 20-082

Study results

Summary results

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