Protein synthesis rates of muscle and bone tissue in femoral bone fracture patients.

Published: 09-12-2020
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To investigate protein synthesis rates and enrichments of femoral bone tissue proximal and distal to a hip fracture.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON49997

Source
ToetsingOnline

Brief title
FEmoral BOne fracture study (FEBO)

Condition

- Other condition
- Fractures

Synonym
Hip fracture, proximal femoral fracture

Health condition

Eiwitmetabolisme in verschillende musckuloskeletale weefsels

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Bone, Hip fracture, Protein synthesis rates, Skeletal Muscle

Outcome measures

Primary outcome

The primary outcome parameters are 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 skeletal muscle, expressed in FSR (%/h). In addition, plasma enrichments of L-[ring-13C6]-phenylalanine is a secondary outcome parameter.

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

To investigate protein synthesis rates and enrichments of femoral bone tissue proximal and distal to a hip fracture.

Study design

Prospective observational study.

Study burden and risks

The burden for participating patients is minimal.
The only additional actions that are required in addition to routine care are the intravenous infusion of a stable isotope amino acid solution 2.5 h before surgery untill the end of surgery and sampling of blood through a catheter. The insertion of the catheter can cause a hematoma.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-01-2021
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	09-12-2020
Application type:	First submission
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	NL75424.068.20
Other	wordt geregistreerd na positief besluit