Full weight bearing after acetabular fractures: A proof of concept study

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The aim of this study is to investigate the safety of immediate full weight bearing after acetabular fractures.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON47224

Source
ToetsingOnline

Brief title
Full weight bearing after acetabular frature

Condition

- Bone and joint therapeutic procedures

Synonym
Acetabular fracture

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,DePuy Synthes

Intervention

Keyword: Acetabular, Fracture, Full weight bearing

Outcome measures

Primary outcome

Primary endpoint:

Fracture dislocation measured in mm by Low Dose CT-scan.

Secondary outcome

Secondary endpoint:

Functional status 12 weeks post surgery, measured by the Merle d*aubigné

score

General heath 12 weeks post surgery, measured by the SF-36

Study description

Background summary

Treatment of displaced acetabular fractures involves a period of non weight bearing for 8 to 12 weeks. This regime of non weight bearing has multiple disadvantages: the energy needed for mobilizing non weight bearing is 4 times higher than mobilize weight bearing, development of muscle atrophy after immobilization and longer time till full recovery. In all 313 patients treated in our medical center for acetabular fracture, no dislocation of fracture alignment was seen after full weight bearing. These data shows that, in potential, acetabular fractures are treated to conservative with regard to early mobilization. Early mobilization after acetabular fractures would probably lead to multiple advantages.
There are no studies published about the advantages of accelerated weight bearing after acetabular fractures. Studies about accelerated weight bearing after hip surgery showed: less morbidity, less mortality, better independent ambulation, less medical cost, better quality of life and a decreased length of stay compared to normal time to full weight bearing. Immediate full weight bearing after acetabular fractures has potentially the same advantages as after hip surgery en thereby the potential to improve the quality of medical care.

Study objective

The aim of this study is to investigate the safety of immediate full weight

bearing after acetabular fractures.

Study design

Patients will be included on the surgical ward. Patients will receive an information letter preoperatively. After a minimal period of 24 hours patients will be visited again (in case of the operatively treated patient, after the surgery when the patients is fully conscious. They will be asked if they have any question regarding the study. Whenever the patient feels well informed about the study and willing to participate, he will be asked to sign the informed consent.

The surgeon who performed surgery will determine if the patient will be enrolled in this study. We know that the decisions is based on a expert opinion instead of objective terms. But factors that influence safety of early weight-bearing are wide spread. For example type of fracture, fracture displacement and bone quality. We will record all drop-outs with the reasons explained by the surgeon.

Post surgery the patient will undergo low dose Pelvic CT control. When the surgical drain is removed patient are allowed to fully load their operated leg. Standard procedure is to remove the drain 2-3 days post surgery.

Patient will come to our outpatient clinic 1,2, 6 and 12 weeks post surgery. A Low Dose CT will be performed for detecting fracture displacement.

Functional score (Merle d*aubigné score) and general health score (SF-36) will be taken after surgery and at the outpatient clinic

Study burden and risks

Patients will be exposed to 5 extra Low Dose CT with a total radiation maximum of 4,5 msV which is the same radiation dose as in normal follow up. Besides radiation patients will be exposed to the risk of fracture displacement after early full weight bearing.
The benefit of this study is that it will be the first study to test early full weight bearing after acetabular fracture. And thereby provide the evidence for other acetabular studies. Early weight-bearing is associated with: less morbidity, less mortality, better independent ambulation, less medical cost, better quality of life and a decreased length of stay compared to normal time to full weight bearing. Participations of this study will have all of these benefits.

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

- Aged between 18 and 65 years
- Operatively treated acetabular fracture
- Mentally competent
- Capable to speak, read and understand Dutch
- Given oral and written informed consent
- surgical treatment of displaced acetabular fracture

Exclusion criteria

- Females who are pregnant, or suspected to be pregnant
- BMI > 35

- A history of an acetabular or pelvic fracture in the past
- Patients with pelvic fractures besides there acetabular fracture
- Fractures in the legs or spine or other injuries that may hinder normal rehabilitation
- Known osteoporoses, defined by a DEXA scan
- Suspected osteoporoses on X-ray
- Intra operatively observed poor bone quality and/or insufficient bone stock for firm osteosynthese observed by the surgeon

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-09-2019
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	15-10-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL56814.091.16