Full weight bearing after acetabular fractures;Evaluation of the accuracy of Low Dose CT for detecting dislocation in patients with acetabular fractures

Published: 22-09-2015
Last updated: 19-04-2024

Evaluation of the accuracy of Low Dose CT for detecting dislocation in patients with acetabular fractures

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Observational invasive

Summary

ID

NL-OMON42341

Source
ToetsingOnline

Brief title
Radiographic control after acetabular fractures

Condition

- Bone disorders (excl congenital and fractures)

Synonym
acetabulur fracture

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Acetabular, CT, Dislocation, Fracture

Outcome measures

Primary outcome

The distance of fracture displacement measured by Low Dose CT compared to the

distance measured on routinely made CT

Secondary outcome

Radiation exposure parameters as measured from the scanners console:

Volume computed tomography dose index (CTDIvol) and Dose Length product (DLP)

in mGy cm, standard deviation, and scanning length for each scan.

In addition on patient height and weight will be collected.

- Image noise (SD) in an region of interest (ROI) in air

- Beam hardening artifacts

Study description

Background summary

The current protocol for patients with internal fixation of acetabular fractures is to mobilize non weight bearing up to 12 weeks. We know from unpublished data that the mean time till full weight bearing is 9 weeks (range 0-13 weeks) in our medical center. No further dislocation was observed in these patients. So this data suggest that time until full weight bearing can be reduced. Whenever a patient starts to mobilize immediately on a weight bearing regime, there is a chance of further dislocation of the fracture. So radiographic control is needed for observing changes in fracture alignment. There is no data available on radiographic control for immediate weight bearing after operatively treated acetabular fractures. So before starting a study on immediate full weight bearing, we need to find out which radiographic control is capable of detecting changes in fracture alignment after immediate full

weight bearing.

Study objective

Evaluation of the accuracy of Low Dose CT for detecting dislocation in patients with acetabular fractures

Study design

In this study two patients will be tested:
1. Patient with ORIF for displaced acetabular fracture
2. Patient who is treated conservatively

The patients will be included on the surgical ward. The patient will receive, preoperatively, an information letter. After 24 hours the patient will be visited again. He will be asked if he has 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.

Routinely patients undergo CT for the diagnosis of acetabular fractures. When a patients is treated operatively they also undergo CT postoperatively.
By participating in our study patients agree to undergo extra Low Dose CT

Fracture dislocation from previously made CT and Low Dose CT will be compared. By doing so we want to determine of Low Dose CT is capable of detecting fracture dislocation precisely.

Study burden and risks

Patients will be exposed to extra radiation of approxitmely 1 mSV.
The International Commission of Radiological Protection considers the radiation exposure of studies with an effective dose of less than 1 mSv as minor category (category IIa.)8 . A study with such a low radiation exposure is expected to have social benefit and that the study is being done to gain knowledge which will lead to potential health improvements.
In addition, there is a time investment for the overall duration of the study of about an half hour.

Contacts

Public
Selecteer

Wolfskuilseweg 18F

Nijmegen 6542JK
NL
Scientific
Selecteer

Wolfskuilseweg 18F
Nijmegen 6542JK
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age 50 years of older on the day the informed consent will be signed
- Male gender
- Mentally competent
- Is capable to speak, read and understand Dutch
- Has given oral and written informed consent
- One operative and one conservative treated patient with an acetabular fracture

Exclusion criteria

- Female gender
- BMI >30
- BMI <18

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-01-2016
Enrollment:	2
Type:	Actual

Ethics review

Approved WMO

Date:	22-09-2015
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	NL53194.091.15