The Quality of Fracture Reduction with the Intra-Operative Use of the 3D-RX-System in fractures of the extremities

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Objective of the study is to asses quality of fracture reduction and patient-relevant outcomes with the intra-operative use of the 3D-RX-system as compared to the conventional 2D-fluoroscopy in patients with traumatic intra-articular fractures of...

Ethical review	-
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON35256

Source
ToetsingOnline

Brief title
EF3X Trial

Condition

- Other condition
- Fractures
- Bone and joint therapeutic procedures

Synonym
and ankle., intra-articular fractures of calcaneus, wrist

Health condition

fractuurdiagnostiek

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Philips,Philips Medical Systems;Best;Nederland

Intervention

Keyword: 3D-imaging, fluoroscopy, fracture reduction, intraoperative

Outcome measures

Primary outcome

1. Quality of fracture reduction on postoperative CT-scans

2. Diagnostic value according to a standard protocol of judging the

postoperative CT-scans and intra-operative 2D-fluoroscopy and

3D-scans. The scores of the intraoperative scans and postoperative

CT-scans will be compared.

3. Cost-effectiveness of 3D-Rx vs. 2D-scanning and CT.

Secondary outcome

• The number and sort of corrections made after 2D-fluoroscopy

• The number and sort of corrections made after a 3D-scan

• The number of revision operations

• The number and sort of complications

• The fluorotime

• The duration of the operation

• The length of the hospital stay expressed in days

• Duration until full mobilization of the joint expressed in weeks

• The range of motion in degrees; for the ankle plantar and dorsal flexion and

in- and eversion; for the wrist the palmar and

dorsal flexion and ulnar and radial deviation after week 6,12 and 26

weeks and at 2 and 5 years postoperatively.

• The strength of the operated joint compared to the contralateral joint after

week 6, 12 and 26,and at 2 and 5 years

postoperatively.

• The clinical outcome by the DASH-score for the wrist and the FAOS-score for

the ankle after week 6,12 and 26, and at 2 and 5

years postoperatively.

• The pain score after 1, 6, 12 and 26 weeks, and at 2 and 5 years

postoperatively by means of the VAS-score.

• The degree of posttraumatic arthrosis at 5 years postoperatively, judged on a

CT-scan of the operated joint

Study description

Background summary

Despite the present surgical and technical knowledge, suboptimal fracture reduction is still a major problem. For the ankle and foot an unsatisfactory fracture reduction is reported after 18-26% of the operations. This may result in severe functional damage of joints and posttraumatic arthrosis, pain, and loss of function of the joint.
In order to achieve anatomical fracture reduction, an optimal view of the position of the bone fragments and fixation material is a necessity. The currently used 2D-fluoroscopy does not provide sufficient insight, in particular in cases with complex anatomy or subtle injury. Postoperative X-ray images or CT-scans frequently show anomalies (e.g. incongruences in the joint surface or screws located intra-articularly), while these were not recognized on the intra-operative 2D-fluoroscopic images.
Unfortunately logistical reasons and radiation dose restrict a CT-scan to postoperative use only. Irregularities then found could lead to a new

operation. Recently the 3D-RX-system was developed, which provides conventional 2D-fluoroscopic images as well as a 3D-reconstruction of the bony structures. Studies in Germany and our own hospital have already proven this modality provides more information which consequently leads to extra corrections in 18-32% of the fracture operations. However, the effect of the extra corrections on the quality of the anatomical fracture reduction has never been investigated.

Study objective

Objective of the study is to asses quality of fracture reduction and patient-relevant outcomes with the intra-operative use of the 3D-RX-system as compared to the conventional 2D-fluoroscopy in patients with traumatic intra-articular fractures of the ankle, calcaneus or wrist. The second aim is to assess the diagnostic value of the 3D-RX- images as compared the CT-scan as reference standard. Also a cost-effectiveness analysis will be performed.

Study design

Multicenter randomised clinical trial.

In first instance only 2D-fluoroscopy is used for the intra-operative imaging, as part of the usual intra-operative diagnostic procedure. The surgeon will then operate until (s)he is satisfied with the fracture reduction and the osteosynthesis. Randomization will determine whether or not the information of the 3D-scan will be made available to the surgeon. If the 3D-scan results will not be made available, the surgeon terminates the procedure. If the information of the 3D-scan is available to the surgeon he can act on the findings and, if necessary, surgical corrections can be made. If the surgeon is satisfied with the operation result a conclusive 3D-RX-scan must be made. In both randomization groups a CT-scan will be performed postoperatively.

All intra-operative images (both 2D-fluoroscopy and 3D-scans) and postoperative CT-scans will be blinded and presented in random order for evaluation by 5 experts. During hospital stay the pain score (VAS-score) will be recorded daily. The follow-up after hospital discharge will be at week 6, 12 and 26, 52 and after 2 and 5 years postoperatively. The range of motion and the functional outcome will be recorded. For the ankle and foot the *Foot and Ankle Outcome Score* (FAOS) will be used for this, for the wrist the *Disabilities of Arm and Shoulder* (DASH) score will be used.

Intervention

All included patients will be subjected to additional intra-operative 3D-RX. In half of the patients the surgeon will be blinded to these results, in the other half the surgeon may use the 3D-RX results to further optimize fracture

reduction.

Study burden and risks

- 1-2 intra-operative 3D-RX-scans
- A CT-scan of the ankle, calcaneus or wrist
- 2 extra X-rays after two and five years
- time investment in filling out questionnaires

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Adults

Traumatic intraarticular fracture of wrist, ankle or calcaneus
Informed consent

Exclusion criteria

Pathological fractures
Mentally or physically unable to comply with the trial requirements

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-10-2009
Enrollment:	700
Type:	Actual

Ethics review

Not available

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	NL28622.018.09