Extremity fractures with intra-operative 3D-RX.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23966

Source
NTR

Brief title
EF3X

Health condition

fracture
ankle
wrist
calcaneus
hindfoot
foot
3D-RX
trauma
3D-scan
breuk
fractuur
enkel
pols
hielbeen
voet

Sponsors and support

Primary sponsor: Trauma-Unit, department of Surgery

Academic Medical Center, Amsterdam
Source(s) of monetary or material Support: Philips Medical Systems, Best, the Netherlands

Intervention

Outcome measures

Primary outcome

For the first aim of the trial, the quality of fracture reduction and fixation of the ankle, calcaneus, or wrist will be assessed by a standard scoring protocol to judge fracture reduction and fixation. The postoperative CT-scans will be used for this score and will be judged by at least 5 experts. The scoring of the images will be in a blinded fashion and in random order. The scores of quality of fracture reduction and fixation will be compared between the intervention group and the control group. The second aim, the diagnostic value, will also be assessed according to a standard scoring protocol as mentioned above with the addition of scoring the image quality. The scores of the intra-operative 3D-scans and postoperative CT-scans will be compared. Judgement of the image quality and diagnostic value will be determined again by 5 experts, as explained above.

Secondary outcome

For the secondary outcomes the number and sort of complications will be recorded and the duration until full mobilization of the joint expressed in weeks. The clinical outcome will be determined by the range of motion in degrees and the DASH-score for the wrist and the FAOS-score for the ankle after 6 and 12 weeks and 1, 2 and 5 years postoperatively.

Study description

Background summary

Despite the present surgical and technical knowledge, suboptimal fracture reduction and fixation is still a major problem. For the ankle and foot an unsatisfactory fracture reduction is reported after 18-26% of the surgical procedures. In order to achieve anatomical fracture reduction, an optimal view of the position of the fracture fragments and fixation material is necessary. The current 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 not recognized on the intra-operative 2D-fluoroscopic images. Irregularities thus found may require a reintervention.

Recently the 3D-RX-system has been developed, which provides conventional 2D-fluoroscopic images as well as a 3D-reconstruction of the bony structures. Previous studies

have shown 3D-RX provides more information, leading to extra corrections during 18–32% of the surgical procedures. However, the effect of these extra corrections on the quality of fracture reduction and fixation, and patient-relevant outcomes has not yet been investigated. In a large international multicenter randomized clinical trial we will assess the quality of fracture reduction and patient-relevant outcomes with the intra-operative use of 3D-RX as compared to conventional 2D-fluoroscopy in centers that already utilize the 3D-RX-system. The second aim is to assess the diagnostic value of the 3D-RX images as compared to the CT-scan as reference standard.
A total of 1000 adult patients with a traumatic intra-articular ankle, calcaneus, or wrist fracture eligible for surgery will be included. Surgeons will operate with 2D-fluoroscopy until the reduction is to their satisfaction. Then patients will be subjected to additional intra-operative 3D-RX. In half of the patients the surgeon will be blinded to the results of the 3D-RX, in the other half the surgeon may use the 3D-RX results to further optimize fracture reduction.
As main study outcomes, the quality of fracture reduction will be assessed on postoperative CT-scans as well as the long-term functional outcome for the patients. Additionally, assessment of the diagnostic value will be performed by comparing the scores of a standard scoring protocol of the reduction, fixation and image quality, postoperative CT-scans will be compared to intra-operative 2D-fluoroscopy and 3D-RX. Thus, evidence will be generated to improve quality of care for patients with such common fractures.

Study objective

In this multicenter RCT we aim to investigate the quality of fracture reduction and fixation, and patient-relevant outcomes when using 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. Our hypothesis is that the quality of fracture reduction and fixation will be better with the intra-operative use of the 3D-RX-system than with conventional 2D-fluoroscopy.

The second aim is to assess the diagnostic value of the 3D-RX- images as compared to the CT-scan as reference standard. With the second aim we hypothesize that the diagnostic value of the 3D-RX-system equal the diagnostic value of the CT-scan.

Study design

Follow up will be directly postoperative, at 6 and 12 weeks postoperative and 1, 2 and 5 years postoperative.

Intervention

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 fracture reduction and osteosynthesis. Then the surgeon will be asked to evaluate the operated joint according to the scoring protocol for fracture reduction and fixation, which is now being developed. After this evaluation a 3D-RX will be performed and

randomization will take place. The 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. This conclusive 3D-RX-scan needs to be evaluated according to the scoring protocol for anatomical reduction. In both randomization groups a CT-scan will be performed postoperatively.

Contacts

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Eligibility criteria

Inclusion criteria

Adult patients (age > 17 years) with a traumatic intra-articular ankle, calcaneus, or wrist fracture eligible for surgery according to the AMC-protocol for fractures in adults will be included. Randomization will be stratified for the different participating centers and the following fracture types: Distal radius fracture, AO-classification A1-C3; distal tibial fracture, AO-classification B1-C3; malleolar fractures, AO-classification A1-C3; and tongue type and joint depression type of calcaneus fractures.

Exclusion criteria

1. If they have pathological fractures, i.e. due to underlying malignant disorder;

2. When patients are unable to understand trial features due to mental or language handicap;

3. No written consent can be obtained.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2009
Enrollment:	510
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	08-07-2009
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	NL1792
NTR-old	NTR1902
Other	METC Academic Medical Center, Amsterdam : MEC 09/171
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A