Is routine radiography following the initial 2-week follow-up of trauma patients with wrist and ankle fractures necessary?

No registrations found.

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

Summary

ID

NL-OMON29076

Source
Nationaal Trial Register

Brief title
WARRIOR-trial

Health condition

distal radius fractures, ankle fractures

pols fracturen, enkel fracturen

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

The primary outcome is area-specific functional status, which for both types of fracture will be measured using Dutch versions of the following questionnaires:

For ankle fractures the Olerud and Molander ankle score (OMAS).

For wrist fractures the Disabilities of the Arm, Shoulder and Hand Score (DASH).

Secondary outcome

- Functional status measured with the American Academy of Orthopaedic Surgeons foot and ankle questionnaire (AAOS) and the Patient Rated Wrist/Hand Evaluation (PRWHE);

- Costs;

- Pain;

- Health-related quality of life (HRQoL);

- Self-perceived recovery;

- Range of motion

- Complications

Study description

Background summary

Background: Extremity fractures such as ankle and wrist fractures are a common and costly health care problem affecting all age groups. The management of patients with these fractures depends on fracture type and loss of congruity of the involved joint; resulting in cast immobilization or operative treatment. Loss of congruity or displacement leading to uneven joint loading, osteoarthritis and a increased probability of a poor functional outcome, should be identified within the first 2 weeks following trauma, based upon conventional radiographic imaging to determine optimal treatment. After this period, routine radiographs and clinical assessments are often scheduled for monitoring the bone-healing process and clinical outcomes, respectively. Many currently used protocols for timing of radiographic assessment describe standard imaging at 1, 2, 6 and 12 weeks following baseline. However, it is questionable whether routine radiography following the initial follow-up (i.e. 2-weeks post trauma) is cost-effective.

The aim of this study is to investigate whether a reduction of the current radiographic follow-

up protocol in patients with uncomplicated wrist or ankle fractures leads to significant cost savings without compromising quality of care.

Methods/design: In a multicentre randomized controlled non-inferiority trial, 418 patients aged 18 years or older will be included, of whom 279 ankle fracture patients and 139 wrist fracture patients. Patients will be randomized in 2 groups. Group 1 is to receive usual care, consisting of routine radiographs at baseline and after 1, 2, 6 and 12 weeks of follow-up. Group 2 is to receive radiographs beyond the initial 2-week follow-up only when clinically indicated. Primary outcome is the extremity-specific functional status, measured using web-based questionnaires. For the ankle fractures the Olerud and Molander ankle score will be used. For the wrist fractures, the Disabilities of the Arm, Shoulder and Hand Score will be used. Secondary outcomes include: Extremity function measured with the American Academy of Orthopaedic Surgeons Foot and Ankle questionnaire (ankle fractures) and the Patient Rated Wrist and Hand Evaluation (wrist fractures), pain intensity, health-related quality of life, self-perceived recovery, and complications such as bone infections, nonunion, malunion, implant failure and costs. Both groups will be monitored clinically at 1,2,6, and 12 weeks and at 6 and 12 months.

Discussion: This study will provide data on (cost-)effectiveness of routine radiography in the follow-up of uncomplicated ankle and wrist fractures, without compromising the quality of care and could pave the way for a change in (inter)national protocols.

Study objective

We hypothesize that a reduction of the current radiographic follow-up protocol for patients with ankle and wrist fractures will lead to significant cost savings without compromising quality of care

Study design

Follow-up at 1,2,6 and 12 weeks, 6 months and 1 year

Intervention

Group 1 is to receive usual care according to the current national protocol, indicating clinical follow-up as well as radiographic evaluations, which shall take place in the outpatient clinics at 1, 2, 6, and 12 weeks.

Group 2 is to receive the same clinical evaluations as the usual care group (see above); however, no routine radiographs will be performed beyond the initial 2 weeks. Radiography during follow-up will be allowed (10% estimated), if any of the following are present: 1) new trauma to the wrist or ankle; 2) pain > 6 based upon the visual analogue scale (11-point VAS); 3) loss of range of motion (ROM) > 20 degrees; 4) neurovascular symptoms; or 5) at the discretion of the clinician

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Eligibility criteria

Inclusion criteria

- Adult (> 18 years);

- Fracture of the ankle (uni-or bimalleolar fractures /Lauge-Hansen classification SA II, SE II-IV, PA I-IV) or fracture of the distal radius (AO classification type A-C);

- Sufficient understanding of the Dutch language

Exclusion criteria

- Psychiatric conditions;

- Pathological fractures;

- Complicated fractures (Gustilo grade 2 & 3);

- Multi-extremity fractures;

- Unable to complete follow-up

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2014
Enrollment:	418
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	26-05-2014
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	NL4477
NTR-old	NTR4610
Other	METC LUMC : P14.086

Study results