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

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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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29076

Bron
Nationaal Trial Register

Verkorte titel
WARRIOR-trial

Aandoening

distal radius fractures, ankle fractures

pols fracturen, enkel fracturen

Ondersteuning

Primaire sponsor: Leiden University Medical Center
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Psychiatric conditions;

- Pathological fractures;

- Complicated fractures (Gustilo grade 2 & 3);

- Multi-extremity fractures;

- Unable to complete follow-up

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-06-2014
Aantal proefpersonen:	418
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	26-05-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4477
NTR-old	NTR4610
Ander register	METC LUMC : P14.086

Resultaten