Operative Treatment of Intra-Articular Distal Radius Fractures With versus Without Arthroscopy a Randomized Controlled Trial

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Fractures
Study type	Interventional

Summary

ID

NL-OMON42637

Source
ToetsingOnline

Brief title
RADAR

Condition

- Fractures

Synonym
intra-articular distal radius fracture, wrist fracture

Research involving
Human

Sponsors and support

Primary sponsor: Maasstadziekenhuis

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

Intervention

Keyword: fracture, intra-articular, ORIF, wrist arthroscopy

Outcome measures

Primary outcome

Patient-Rated Wrist Evaluation (PRWE) score

Secondary outcome

Disability of the Arm, Shoulder and Hand (DASH) score

Pain, as indicated on a Visual Analogue Scale (VAS)

Range of Motion (ROM)

Grip strength (measured with a grip strength meter)

Complications

Costs and absence from work (economic evaluation)

Study description

Background summary

The past several years an increase in open reposition internal fixation (ORIF) for distal radius fractures has been observed. This technique leads to a quicker resume of function the first 3 to 6 months compared to non-operative treatment. However, some patients with a dislocated intra-articular distal radius fracture continue to have a painful and stiff wrist postoperatively. Arthroscopically assisted removal of intra-articular fracture haematoma and debris may improve the functional outcomes following operative treatment of intra-articular distal radius fractures. Moreover, during arthroscopy the quality of the reduction and the presence of associated ligamentous injuries can be assessed.

Study objective

The objective of this randomized controlled trial is to determine the

difference in functional outcome, assessed with the Patient-Rated Wrist Evaluation Score (PRWE), after conventional fluoroscopically assisted plate fixation and plate fixation with an additional arthroscopy in adult patients with displaced intra-articular distal radius fractures.

Study design

(singlecenter) Randomized controlled trial.

Intervention

This study will randomize between a conventional fluoroscopic open reduction and internal volar plate fixation (control group) and the conventional procedure with an additional wrist arthroscopy (intervention group).

Study burden and risks

The treatment that patients will receive is a component of the standard treatment of care, which currently depends on the surgeon*s preference. Patients will be asked to return to the hospital for follow up at one, three and six weeks and three months. All visits are part of standard care following a fracture treated in this hospital. Additionally patients are phoned 1 day post-operative to ask about post-operative pain. During the visits patients will be asked about any complaints and/or complications and physical examination will be performed. The assessment of the range of motion of the wrist will take approximately five minutes. Additional to standard care, patients will be asked to fill out four questionnaires at three and six weeks and three months. Patients will be asked to fill out a PRWE and DASH form, rate their pain on a Visual Analogue Scale and give an estimation of the type and quantity of pain medication taken during all visits. This will take approximately fifteen minutes of their time. Additionally, a questionnaire on any expenses and absence from work will be administered. This will take another ten minutes. Subjects could experience mild discomfort during physical examination and testing, but this will be no different from physical examination during routine follow-up. The burden experienced regarding time spent is difficult to estimate but will most likely not exceed 30 minutes. In the total duration of this study, patients will spend an approximate 90 minutes extra.

The risks are comparable to those that the standard treatment involves. This comprises the standard risk for undergoing a surgical procedure, including risks related to anesthesia, neurovascular damage and post-operative wound infection. Patients undergoing an arthroscopic assisted procedure will have a longer duration of the operation time, about 40 minutes. Possible complications of wrist arthroscopy include infection, articular surface damage, injury of one of the nerves and tendon rupture. Nevertheless, wrist arthroscopy is a

well-established and safe technique. Close follow up and a protocol of treatment, identical to the standard one, will be applied in every subject. Reduction of risks will be done according to inclusion and exclusion criteria. If complications arise, the treating physician will proportionate the adequate treatment according to the current protocols of treatment based on the published literature.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patient from 18 years or older with a displaced complete articular distal radius fracture (AO type C), requiring open reduction and internal fixation with a volar locking plate

Exclusion criteria

• Patients with impaired wrist function prior to injury due to arthrosis/neurological disorders of the upper limb
• Open distal radius fractures
• Multiple trauma patients (Injury Severity Score (ISS) >=16)
• Other injuries in the ipsilateral extremity (except ulnar styloid process)
• Fracture of contralateral wrist
• Insufficient comprehension of the Dutch language to understand a rehabilitation program and other treatment information as judged by the attending physician
• Patient suffering from disorders of bone metabolism other than osteoporosis (i.e. Paget*s disease, renal osteodystrophy, osteomalacia)
• Patients suffering from connective tissue disease or (joint) hyperflexibility disorders such as Marfan*s, Ehler Danlos or other related disorders

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-02-2016
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	28-10-2015
Application type:	First submission

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL54377.101.15