Functional outcome of conservative treatment of distal radius fractures: Dorsal flexion versus palmar flexion, the D-FLEX trial. A prospective randomized controlled trial

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Primary Objective: Our main goal is to determine whether dislocated distal radius fractures immobilized in dorsoflexion gives a better functional outcome in comparison to immobilisation with the wrist in palmarflexion. For this we will use the quick...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Fractures
Study type	Interventional

Summary

ID

NL-OMON37606

Source
ToetsingOnline

Brief title
D-FLEX trial

Condition

- Fractures

Synonym
colles' fracture, wrist fracture

Research involving
Human

Sponsors and support

Primary sponsor: Kennemer Gasthuis
Source(s) of monetary or material Support: Research fonds Kennemer Gasthuis (Posthumus Meijus fonds)

Intervention

Keyword: Colles' fracture, conservative treatment, functional outcome, randomized controlled trial

Outcome measures

Primary outcome

Disabilities of the Arm, Shoulder and Hand score (quick DASH-score)

Quick DASH is a self-administered questionnaire that was developed in Canada in 2006, and can be used instead of the full DASH with similar precision (gummeson). This short version can improve the response rate (Abramo). A Dutch version has been validated for use in upper extremity disorders. The questionnaire consists of 11 questions evaluating different aspects of physical activity, severity of symptoms and the effect of the injury on social activities. A score is calculated and the disability of the patient is estimated on a scale from 0 to 100, with 100 being the worst result. The patients are asked to complete the form on week 7,9 15 en 26.

Secondary outcome

Range of motion

A goniometer is used for the measurement of the flexibility of wrist and finger joint of the healthy hand and injured hand not sooner than 7 weeks after closed

reduction. And also at 9,15 and 26 weeks extension, flexion, pronation and

suppination will be measured.

Anatomical evaluation

Postero-anterior and lateral radiographs are used to determine radial tilt,

ulnar variance and palmar tilt before reduction and immediately after and at

follow-up. (at 5 days, 10 days, 5 weeks)

Acceptable anatomical positions:

- Radial shortening: level radius >= level ulna

- Normal articulation distal radio-ulnar joint (DRUJ)

- Dorsal angulation 10* until -20*

- Radial inclination > 15* and < 35*

Study description

Background summary

Fractures of the distal radius (Colles*fractures) are one of the most common fractures seen on the Accident and Emergency department.(1) This type of fracture occurs most commonly between the age 6 and 10, and between the age 60 and 69 (Joskosmilovic=2). In the group of patients aged above 60, women suffer this type of fracture nearly 7 times more often than men. The majority (75-85%) of distal radial fractures are treated non-operatively (2-4). Especially among the elderly where there is a lower functional need and the risks during operation are higher. The final choice of treatment method will be influenced by many considerations including the nature of the fracture, bone stock and fragility, the presence of local complications, the patients general medical condition, the expected functional loading and patient motivation. (Cochrane revieuw=3)

These fractures are typically displaced and angulated dorsally and radially with shortening of the distal part of the radius. If they are allowed to unite in poor anatomical alignment, a poor functional outcome is more likely (earnshaw =1). AO- classification is the most commonly used for describing these fractures. Where type A and B is considered stabile, and type C to be unstable and therefore more prone for surgical intervention. Common practice is to attempt a closed reduction to restore fracture alignment and if possible treated conservative. There is a primary operation indication if the reduction is not sufficient or redisplaced.
The risks of conservative treatment are secondary dislocation and longterm immobilization with possible loss of function of the wrist and fingers. Compared to the disadvantages of surgical treatment such like woundinfection, infected osteosynthesis material, lesion of radial nerve and artery next to the risk of general anesthetics.

An optimal longterm functional outcome of closed treatment of a Colles fracture may depend on accurate reduction and adequate immobilization. (2,8) There is no agreement on the best way to maintain the reduction in cast. (9-10) A wide variety of methods have been described, including reduction and immobilisation of the wrist and forearm in various positions.(15) Common practice in the conservative treatment of distal radius fractures is to immobilize below elbow with wrist in palmarflexion and ulnar deviation. As thought to be the best method of maintaining the reduction of the dorsal angulated fracture. (6).

In previous studies the rates of loss in anatomical position is often used to determine the effectivity of treatment method. Where restoration of the radial length is an important factor in achieving a good result. In some studies the functional results did not correlate with the radiographic evidence of deformities, suggesting the importance of determining functional outcome as effectivity of treatment as well. (Koji=4)
When the wrist is immobilised in palmar flexion, there is a risk of stiffness and loss of function of the fingers, and especially the metacarpophalangeal joint. (2,11) So the question rises if there is another position of immobilisation in cast that improve the functional and radiological outcome of distal radial fractures.

The main problem of treating Colles* fracture is the maintenance of reduction. This is partly due to its anatomical site, adjacent to the multilinked system of the carpus. Several studies describe the prominent role of ligamentotaxis in (maintenance of) reduction of distal radius fractures (12-13). Ligamentotaxis is the modelling of fracture fragments by using longitudinal traction of the surrounding soft tissue, i.e. the ligaments. How can this ligamentotaxis be obtained and used to maintain reduction besides the effect of the cast? In different studies (Agee, Gupta and Blatter) 13-15 they discribed a biomechanical model when the wrist is dorsiflexed the volar radiotriquetral and radiocapitate ligaments become taut: these stabilise both rows of the carpus with respect to the radius, and resist any deforming forces by providing

a volar pull on the distal fracture fragment. (Fig*.)

These two trials IBlatter 1994:Gupta 1991) involving 254 people with displaced fractures compared wrist positioning in either palmar flexion or neutral with dorsiflexion. Anatomical results for both trials were better in the dorsiflexion group. Overall functional outcome was also better in the dorsiflexion group as shown by the lower proportion of patients with a poor or only fair overall outcome or significant disablitity. Gupta reported without data, that the palmar flexion group had the most redisplacements, and more hand joint stiffness.

Searching the guidelines for treating distal radius fractures there is no robust evidence at present to suggest that one immobilisation position is superior to another.(Cochrane review)

In this prospective randomized controlled trial we will compare the common treatment of distal radial fracture with the wrist immobilised in palmar flexion versus immobilising in dorsal flexion using a validated subjective outcome instrument.

Study objective

Primary Objective:
Our main goal is to determine whether dislocated distal radius fractures immobilized in dorsoflexion gives a better functional outcome in comparison to immobilisation with the wrist in palmarflexion.
For this we will use the quick Disability of the Arm, Shoulder and Hand score (quick DASH score)
In particularly older patients there is a discrepancy between the functional and radiological outcome, most likely due to there lower functional needs.

Secondary Objective(s):
1. Range of motion. A goniometer is used for the measurement of the flexibility of wrist and hand joints of the healthy and injured hand

2. Anatomical assessment. The occurrence of loss of reduction, defined as radiologic slippage or the need for surgical fixation during the first weeks after initial successful reduction.

Study design

The proposed study is a single center, randomized controlled clinical trial comparing two conservative treatment strategies for dislocated distal radius fractures. Patients will be randomly allocated to A) immobilisation in dorsoflexion or B) immobilisation in palmarflexion.

The proposed starting date is 1-12-2011 and accrual will take place for 10 months. Follow-up will take place for 6 months.

Intervention

Both groups are treated in the same way as far as anaesthesie and reduction were concerned. The only difference in treatment lay in the position of fixation in cast. Group 1: the wrist immobilized in dorsal flexion. Group 2: the wrist immobilized in palmar flexion.

Study burden and risks

Benefits:
- Closed reduction is performed by an experienced orthopaedic cast technician
- In comparison to a splint cast applied on the ED, on the cast room circular splitted cast will be applied to maintain reduction.

Risks:
- During evening and nights the reduction will be prosponed (<24 hours). Untill reduction is performed a cast will be applied. According the literature this will give no extra harm to the patient (function/reduction)(Mc Millan).

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

> 18 years of age
Displaced colles' fracture
Normal wristfunction before fracture

Exclusion criteria

1. A history of wristfracture
2. bilateral wrist fracture
3. Antebrachi fracture type (combination with ulna, proc. stiloideus excluded)
4.palmarly angulated fracture
5. open fracture or tendon/nerve/vascular lesions
6. fracture more than 5 days old
7. Marked comminution or displacement considered for primary surgical fixation
8. Degenerative musculoskeletal disease (osteoporosis excluded)
9. Those who are unable to give written informed consent (mentally disabled, language problem)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-11-2012
Enrollment:	132
Type:	Actual

Ethics review

Approved WMO

Date:	02-07-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL38485.094.11