

DR PIP II: Distal Radius Plaster Immobilization Period II

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23219

Source

NTR

Brief title

DR PIP II

Health condition

Distal radial fracture / distale radius fractuur / polsfractuur
DASH / PRWE / functionele uitkomst / stijfheid / functiebeperking
Dislocatie, range of motion

Sponsors and support

Primary sponsor: VU Medical Center

Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

the QuickDASH (Disabilities of the Arm, Shoulder and Hand) score, and PRWE (Patient Related Wrist Evaluation) score after one year

Secondary outcome

1. Functional outcome (QuickDash/PRWE) after 8 weeks, 3 months and 6 months
2. Range of motion
3. Pain level
4. Lidström-score
5. Fracture related complications

Study description

Background summary

Up to 30% of patients with a dislocated distal radius fracture suffer from long-term functional restrictions following conservative treatment. It remains unclear, whether duration of cast immobilisation influences functional outcome. The aim of the study is to evaluate whether the functional outcome of dislocated distal radial fractures could be improved by shortening the period of immobilization so that reactivation can start earlier. In this study a four weeks of plaster cast immobilization period is compared with six weeks of immobilization for adult patients with reduced distal radial fractures.

The expectation of this study is that shorter duration of plaster cast immobilization is beneficial for the patients. This risk of specific complications is low and generally similar in both treatment options. Follow-up is standardized according to current trauma guidelines; present literature indicates that both treatment options from this study are accepted protocols for treatment of displaced distal radius fractures. This trial will provide level-1 evidence for the comparison of functional outcome between the two treatment options for dislocated distal radial fractures.

Study objective

The expectation of this study is that shorter duration of plaster cast immobilization is beneficial for the patients.

Study design

6 weeks - 12 weeks - 6 months - 1 year

Intervention

four versus six weeks of cast immobilization

Contacts

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Eligibility criteria

Inclusion criteria

1. Age > 18 years;
2. Primary displaced unilateral fracture of the distal radius;
3. Independent for activities of daily living.

Exclusion criteria

1. Fracture of contralateral wrist;
2. Other fractures at the ipsilateral upper extremity (excluded fractures of the hand and fractures of the styloid process of the ulna);
3. Pre-existent abnormalities or functional deficits of the fractured wrist;

4. Open fractures.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-10-2017
Enrollment:	70
Type:	Anticipated

Ethics review

Not applicable	
Application type:	Not applicable

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

NTR-new

NTR-old

Other

ID

NL6423

NTR6600

: Volgt

Study results