

Slijtage van het polsgewricht na een gebroken pols in ouderen

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26024

Source

NTR

Brief title

DART II

Health condition

distal radius fracture

Sponsors and support

Primary sponsor: Reinier de Graaf Gasthuis

Source(s) of monetary or material Support: ReumaNederland

Intervention

Outcome measures

Primary outcome

Radiological degree of radiocarpal osteoarthritis using the SLAC classification.

Secondary outcome

- Patient-Rated Wrist Evaluation score (PRWE)

- Disability of the Arm, Shoulder and Hand (DASH)
- Michigan Hand Outcome Questionnaire (MHOQ)
- Pain Catastrophizing Scale (PCS)
- 15D
- Quality of life (EQ-5D)
- Costs questionnaire
- ROM (range of motion)
- Grip strength
- Complications
- Radiographic parameters
- Frailty score (Groningen Frailty indicator)

Study description

Background summary

Rationale: Continuing controversy exists in the best treatment of intra-articular distal radius fractures in the elderly. The ultimate aim of treatment is to restore articular congruity to prevent complications such as secondary post-traumatic osteoarthritis. Treatment of choice depends highly on the surgeon's preference and functional demands of the elderly patient. Currently, the development of post-traumatic osteoarthritis is unclear regarding the relation to trauma as well as regarding the best treatment. Furthermore, the development of osteoarthritis in relation to the healthy contralateral side (which projects the natural course of osteoarthritis) and in relation to functional outcomes in the elderly are not known.

Objective: Assessing the post traumatic and degenerative radio-carpal osteoarthritis of open reduction and internal fixation compared with non-operative treatment for elderly patients with an intra-articular distal radius fracture.

Study design: A prospective cohort study with a four year follow up study on the DART study (The effectiveness of surgery versus casting for elderly patients with Displaced distal intra-Articular Radius fractures. A randomized controlled Trial).

Study population: Subjects of the DART study (patients aged between 65 years and older with displaced intra-articular distal radius fractures, with an unacceptable reduction fracture characteristics within 3 weeks following trauma).

Intervention (if applicable): Not applicable. Patients have been randomized between open reduction and internal fixation (intervention group) and plaster immobilization (control group) during the DART study.

Main study parameters/endpoints: The degree of radio-carpal osteoarthritis will be evaluated 2 and 5 years after the intra-articular distal radius fracture on X-ray and on CT scan. An assessment will be made if there is a correlation between the primary outcome and secondary outcomes, such as patient reported outcome measures (PROMs) including the

Patient-Rated Wrist Evaluation score (PRWE), Disability of the Arm, Shoulder and Hand (DASH), Michigan Hand Outcome Questionnaire (MHOQ), Quality of life (EQ-5D and 15D) and Pain Catastrophizing Scale (PCS). Further secondary outcomes are the frailty score, range of motion (ROM), grip strength, complications and additional costs as a result of osteoarthritis.

Study objective

- Cast treatment is not inferior to surgical open reduction internal fixation in terms of post-traumatic radio-carpal osteoarthritis and patient related outcome measurements.
- No correlation is present between the radiological degree of post-traumatic radio-carpal osteoarthritis and functional outcomes.

Study design

T1: 2 years post trauma

T2: 2.5 years post trauma (only EQ-5D, costs questionnaire)

T3: 3 years post trauma (only EQ-5D, costs questionnaire)

T4: 3.5 years post trauma (only EQ-5D, costs questionnaire)

T5: 4 years post trauma (only EQ-5D, costs questionnaire)

T6: 4.5 years post trauma (only EQ-5D, costs questionnaire)

T7: 5 years post trauma

Intervention

X-rays of both wrist

CT-scans of both wrists

Contacts

Public

Reinier de Graaf Gasthuis

Malou Slichter

0031 15 260 3819

Scientific

Reinier de Graaf Gasthuis

Malou Slichter

0031 15 260 3819

Eligibility criteria

Inclusion criteria

- Participant of the DART study
- Mentally competent
- Dutch fluency and literacy
- Informed consent

Exclusion criteria

- Participants of the DART study who did not complete the follow-up period
- Fracture of the contralateral wrist in the history
- Rheumatoid arthritis

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	05-03-2019
Enrollment:	126
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date: 05-10-2018

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49854

Bron: ToetsingOnline

Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7308
NTR-old	NTR7524
CCMO	NL67693.098.18
OMON	NL-OMON49854

Study results