# DART II. Post-traumatic osteoarthritis of the wrist in elderly patients with displaced intra-articular distal radius fractures. A follow-up study of the DART trial.

Published: 23-01-2019
Last updated: 15-05-2024

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.

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Bone and joint therapeutic procedures |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON49854

**Source**
ToetsingOnline

**Brief title**
DART II

### Condition

- Bone and joint therapeutic procedures

**Synonym**
articular degeneration after trauma, posttraumatic osteoarthritis

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Reinier de Graaf Groep
**Source(s) of monetary or material Support:** ReumaNederland

## Intervention

**Keyword:** degeneration, distal radius fracture, intra-articular fracture, post-traumatic osteoarthritis

## Outcome measures

### Primary outcome

The degree of radio-carpal osteoarthritis on X-ray and and CT scan 2 and 5

years after the intra-articular distal radius fracture.

### Secondary outcome

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-3L 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 description

### Background summary

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.

### Study 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) (NL56858.100.16, R16.013/DART).

### Study burden and risks

All study patients of the DART study will be approached and asked to participate in the DART II study. As part of the DART II, patients will have two follow-up moments at 24 months and 60 months. Patients will be asked to fill out the questionnaires, both wrists will be physically examined and X-rays of both wrists will be made. Furthermore, at 60 months follow up, a CT scan will be made of both wrists. Patients are also asked to fill out a cost questionnaire combined with the EQ-5D-3L every six months. In total study participants will spend 210 minutes to this study.
Exposure to radiation due to the extra radiographs and CT scan of the wrists is relatively low. In total it will result in approximately 0,044 mSv of radiation.

## Contacts

**Public**
Reinier de Graaf Groep

Reinier de Graafweg 5
Delft 2625 AD
NL
**Scientific**
Reinier de Graaf Groep

Reinier de Graafweg 5
Delft 2625 AD
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Elderly (65 years and older)

## Inclusion criteria

Participant of the DART study or NITEP Nordic Radius study (AO type C fracture)
Mentally competent
Dutch fluency and literacy
Informed consent

## Exclusion criteria

Incomplete follow-up period during participation of the DART study
Fracture of the contralateral wrist in the history
Rheumatoid arthritis

# Study design

## Design

**Study type:** Observational invasive

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Basic science |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 24-05-2019 |
| Enrollment: | 154 |
| Type: | Actual |

# Ethics review

Approved WMO

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| Date: | 23-01-2019 |
| Application type: | First submission |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden) |
| | metc-ldd@lumc.nl |

Approved WMO

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| Date: | 01-05-2019 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden) |
| | metc-ldd@lumc.nl |

Approved WMO

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|---|---|
| Date: | 21-10-2019 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden) |
| | metc-ldd@lumc.nl |

Approved WMO

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|---|---|
| Date: | 09-12-2019 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden) |
| | metc-ldd@lumc.nl |

Approved WMO

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|---|---|
| Date: | 19-05-2020 |

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| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br>metc-ldd@lumc.nl |

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|---|---|
| Approved WMO Date: | 29-09-2020 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br>metc-ldd@lumc.nl |

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|---|---|
| Approved WMO Date: | 29-01-2024 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br>metc-ldd@lumc.nl |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26024
Source: NTR
Title:

## In other registers

| Register | ID |
|---|---|
| ClinicalTrials.gov | NCT03009890 |
| CCMO | NL67693.098.18 |
| OMON | NL-OMON26024 |