The effectiveness of surgery versus casting for elderly patients with Displaced inta-Articular distal Radius fractures. A randomized controlled Trial.

Published: 12-07-2016
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Assessing the (cost)-effectiveness of operative treatment compared with non-operative treatment for elderly patients with an intra-articular distal radius fractures.

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

Summary

ID

NL-OMON55668

Source
ToetsingOnline

Brief title
DART - Surgery vs. Casting for Articular Radius Fractures in Elderly

Condition

- Fractures

Synonym
Intra-articular distal radius fracture / Broken wrist

Research involving
Human

Sponsors and support

Primary sponsor: Orthopedie
Source(s) of monetary or material Support: ZonMw (cofinanciering Zorgverzekeraars

Nederland) / Evaluatieonderzoek ZE&GG

Intervention

Keyword: Articular, Elderly, Radius

Outcome measures

Primary outcome

The primary outcome will be evaluated after 1 year with the Patient-Rated Wrist Evaluation score (PRWE).

Secondary outcome

Secondary outcomes comprise other PROMs including the Disability of the Arm, Hand and Shoulder (DASH), Quality of life (EQ-5D), Patient health (SF-12) and Pain Catastrophizing Scale (PCS). Radiographic parameters and Complications will be evaluated.

Study description

Background summary

It is unclear how intra-articular fractures in elderly patients should be treated. To ensure optimal functional outcome there is a tendency to operate. However, there is no evidence that supports the surgical treatment of patients 65 years and older and in the absence of clinical trials it stays unclear how patients >65 with intra-articular fractures should be treated.

Study objective

Assessing the (cost)-effectiveness of operative treatment compared with non-operative treatment for elderly patients with an intra-articular distal radius fractures.

Study design

Multi-Centre randomized controlled trial with a non-inferiority design.

Economic evaluation alongside a randomized controlled multi-center trial.

Intervention

Patients will be randomized between surgery (open reduction internal fixation) or conservative treatment (casting).

Study burden and risks

The treatment that study participant receive is a component of standard treatment of care. Prior research suggests there is no difference in long-term function between both treatment groups. Currently the choice of treatment is based on the preference of the surgeon, the complexity of the fracture and the national guideline for the treatment of radius fractures.
Post-operatively or after cast therapy patients will be seen after 1 week, 3 weeks, 6 weeks, 3 months, 6 months and 12 months. These visits are standard care for patients following a fracture. In all these visits patients will be asked about complaints or complications, which is also part of regular care.
At baseline and after 6 weeks, 3 months, 6 months and 12 months patients will be asked to fill out 6 questionnaires mentioned earlier as the main study parameters. These questionnaires can be filled out at home online or in the hospital prior to their visit and will take approximately 30 minutes for each of these data collection moments.
In total study participants will spend 210 minutes to this study. This includes informed consent.
The risks of this study are comparable to risks involved with standard treatment. This comprises the standard risk for undergoing a surgical procedure, including risks related to anesthesia, neurovascular damage and post-operative wound infection. The risks of closed reduction and plaster immobilization include stiffness, redislocation, malunion, loss of function and complex regional pain syndrome.
Possible complications will be treated according to standard protocol.

Contacts

Public
Selecteer

Oosterpark 9
Amsterdam 1091 AC
NL
Scientific
Selecteer

Oosterpark 9
Amsterdam 1091 AC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

- Intra-articular radius fracture
- Age 65 and older

Exclusion criteria

* Open fractures
* AO type A (Extra-articular fractures)
* AO type B fractures (Partially articular fractures)
* Neurovascular damage
* Multiple-trauma patients (ISS >16)

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:	Recruitment stopped
Start date (anticipated):	01-02-2017
Enrollment:	114
Type:	Actual

Ethics review

Approved WMO Date:	12-07-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-01-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-03-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-03-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	09-05-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	23-05-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-07-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-09-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-09-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-03-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-07-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-09-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-12-2021
Application type:	Amendment

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	NL56858.100.16