A Randomised Controlled Trial of Nonoperative Treatment versus Open Reduction and Internal Fixation for Mason type-II Fractures Of the Radial Head

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

Summary

ID

NL-OMON41363

Source
ToetsingOnline

Brief title
Rambo

Condition

- Fractures

Synonym
fracture of the head of the laterale bone of the forearm, radial head fractrure

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: AO research grant

Intervention

Keyword: fracture, nonoperative treatment, radial head, surgical treatment

Outcome measures

Primary outcome

The main study parameter is the change in DASH from baseline to endpoint (12 months later), in both groups.

Secondary outcome

The secundary study parameter is the change in OES and MEPI from baseline to endpoint (12 months later), in both groups.

Study description

Background summary

Displaced partial articular fractures of the radial head are classified as Mason type-II fractures. Open reduction and internal fixation remains a popular treatment for isolated, stable displaced partial fractures of the radial head, while there is no Level I or II evidence for optimal management of these fractures. We will compare ORIF vs. nonoperative management in the treatment of isolated, stable displaced partial fractures of the radial head.

Study objective

The primary objective of this study is to compare the DASH (Disabilities of the Arm, Shoulder, and Hand) after conservative treatment versus ORIF in adult patients who sustained a Mason type-II fracture of the radial head. Secondary aims are to examine the effect of conservative treatment versus ORIF on functional outcome (Mayo Elbow Performance Index (MEPI) and Oxford elbow scores (OES), the level of pain (Visual Analog Scale (VAS)), ROM (flexion arc and rotational arc), the rate of secondary interventions and complications.

Study design

Randomized controlled trial

Intervention

Patients that are assigned to non-operative management will get a sling for comfort and are instructed to start active and active-assisted range of motion exercises the same day. Patients that are assigned to ORIF will be treated by screw fixation of the displaced partial articular fracture fragment. Patients in both groups have the possibility to train under physical therapist guidance according to study protocols.

Study burden and risks

Based upon current scientific literature, there is no clear preference for one of the two treatments that patients can be assigned to in this study. Both forms of treatment are regularly applied for these fractures in each of the participating institutions and all surgeons participating in this study are familiar with nonoperative and operative management of radial head fractures. Patients will be exposed to radiation from radiographs. However, this exposure is part of routine clinical care and represents no increased risk. There are no extra radiographs taken as part of this study. The risks and discomfort of participating in this study do not exceed those of standard treatment for this condition.

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

Age 18 years or older.
A maximum of 10 days after the trauma.
Fracture fragment size estimated at least 30% of the articular surface.
At least 2 millimeters step of the articular surface on at least one radiographic view.
Fracture amenable to screw fixation.
Provision of informed consent by patient

Exclusion criteria

Associated fracture or dislocation of the elbow or forearm.
Polytraumatized patients.
Cognitive deficits (closed head injury, coma, etc.) that prevent participation in rehabilitation.
History of operations or fractures of the involved elbow
Patients not amenable for operative treatment and/or general anaesthesia.

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):	03-09-2012
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	20-02-2012
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	16-04-2013
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	23-09-2014
Application type:	Amendment
Review commission:	METC St Elisabeth Ziekenhuis (Tilburg)
Approved WMO Date:	11-05-2015
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	28-06-2017
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL38903.008.11