Operative vs. nonoperative treatment of Mason type 2 Radial Head Fractures: A multicenter randomized controlled trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27653

Source
Nationaal Trial Register

Brief title
RAMBO trial

Health condition

Radial head fractures, Mason 2, open reduction internal fixation, elbow

Sponsors and support

Primary sponsor: Trauma Unit, Department of Surgery, Academic Medical Center, Amsterdam
Source(s) of monetary or material Support: Academic Medical Center, Amsterdam

Intervention

Outcome measures

Primary outcome

DASH score.

Secondary outcome

1. Oxford Elbow Score;

2. Mayo Elbow Performance Index.

Study description

Background summary

Fractures of the radial head are commonly classified according to the classification by Mason1 as modified by Broberg and Morrey. Nondisplaced or minimally displaced fractures are classified as Mason type 1 and are usually treated nonoperatively. Fractures with a gap of more than 2 mm or fractures that comprise more than 1/3 of the articular surface are defined as Mason type 2 fractures. Mason type 3 fractures are severely comminuted radial head fractures and are most commonly treated operatively. For displaced, isolated partial articular fractures (Mason type 2), the choice of treatment is subject to discussion, partially due to the absence of level 1 evidence. Previously, these fractures were treated nonoperatively; if treatment failed, radial head excision would be performed. Nowadays, the tendency lies towards open reduction and internal fixation of isolated displaced partial articular radial head fractures. In this multicenter prospective randomized trial, we will compare ORIF by means of screw fixation vs. nonoperative management in the treatment of Mason type two fractures of the radial head. The primary objective of this study is functional outcome measured by the Disabilities of Arm, Shoulder and Hand (DASH) Score in adult patients after one year. Secondary outcomes are Mayo Elbow Performance Index (MEPI) and Oxford Elbow Score (OES) as well as the level of pain measured by means of a Visual Analog Scale (VAS), Range of Motion (ROM), flexion arc and rotational arc. Complications such as arthrosis, subsequent or revision surgery, neurovascular compromise and infections will be recorded.

Study objective

Null hypothesis: Patients with a Broberg and Morrey modified Mason type 2 radial head fracture that are treated nonoperatively have the same outcomes in terms of DASH scores after 6 months as opposed to patients that are treated with open reduction and internal fixation.

Study design

Postoperative follow-up:

3 months, 6 months, 1 year.

Intervention

This study will randomize between:

1. Direct open reduction and internal fixation;

2. Nonoperative treatment.

Contacts

Public
Academisch Medisch Centrum
Marjolein Mulders
Amsterdam 1100 DD
The Netherlands
+31628243430
Scientific
Academisch Medisch Centrum
Marjolein Mulders
Amsterdam 1100 DD
The Netherlands
+31628243430

Eligibility criteria

Inclusion criteria

1. 18 years of age;

2. Radial Head Fracture Broberg and Morrey modified Mason 2 = a two part fracture with >30% of the articular surface involved, and a >2mm displacement in any direction;

3. Diagnosis based on an AP and Lateral X-ray (with additional Greenspan view if necessary);

4. Fracture suited for screw fixation;

5. Treatment possible <10 days after date of injury.

Exclusion criteria

1. Multiple Other Fractures;

2. Open fracture;

3. Radial head fracture as part of an elbow dislocation;

4. A nondisplaced or comminuted fracture (Mason1 or 3);

5. Previous ipsilateral olecranon/distal humerus/radial head fracture;

6. Suspected osteolytic malignancy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2012
Enrollment:	80
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	02-05-2012
Application type:	First submission

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
NTR-new	NL3260
NTR-old	NTR3413
Other	ABR : 40714
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

1. Broberg MA, Morrey BF. Results of delayed excision of the radial head after fracture. J Bone Joint Surg Am 1986;68:669-674.
2. Broberg MA, Morrey BF. Results of treatment of fracture-dislocations of the elbow. Clin Orthop Relat Res 1987:109-119.
3. Calderon SA, Zurakowski D, Davis JS, Ring D. Quantitative Adjustment of the Influence of Depression on the Disabilities of the Arm, Shoulder, and Hand (DASH) Questionnaire. Hand (N Y) 2009. doi:10.1007/s11552-009-9205-8
4. Chow SC LJ. Design and analysis of clinical trials: concepts and methodologies. New York: John Wiley & Sons; 1998.
5. Mason ML. Some observations on fractures of the head of the radius with a review of one

hundred cases. Br J Surg 1954;42:123-132.
6. Rosenberger W LJ. Randomization in clinical trials: theory and practice. New York: Wiley-Interscience; 2002.
7. Zarattini G, Galli S, Marchese M, Mascio LD, Pazzaglia UE. The surgical treatment of isolated mason type 2 fractures of the radial head in adults: comparison between radial head resection and open reduction and internal fixation. J Orthop Trauma 26:229-235. doi:10.1097/BOT.0b013e318220a227