

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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27653

Bron

Nationaal Trial Register

Verkorte titel

RAMBO trial

Aandoening

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

Ondersteuning

Primaire sponsor: Trauma Unit, Department of Surgery, Academic Medical Center, Amsterdam

Overige ondersteuning: Academic Medical Center, Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

DASH score.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Postoperative follow-up:

3 months, 6 months, 1 year.

Onderzoeksproduct en/of interventie

This study will randomize between:

1. Direct open reduction and internal fixation;
2. Nonoperative treatment.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2012
Aantal proefpersonen:	80
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum: 02-05-2012

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3260
NTR-old	NTR3413
Ander register	ABR : 40714
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

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.

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