PROMOTION-trial: onderzoek naar 2 verschillende chirurgische methoden om een verplaatste breuk van de bovenarm te behandelen.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24602

Source
NTR

Brief title
PROMOTION-trial

Health condition

bovenarmbreuk
humerus fracture

Sponsors and support

Primary sponsor: Maastricht University Medical Center
Source(s) of monetary or material Support: Maastricht University Medical Center

Intervention

Outcome measures

Primary outcome

Primary endpoint is functional outcome 1 year after surgery indicated by the Constant-Murley scale.

Secondary outcome

Secundary outcomes are DASH-score, pain, SF-12, EQ-5D, complication and mortality rate.

Study description

Background summary

With an aging population the incidence of humerusfractures will rise. Dislocated 3-part proximal humerus fractures are treated either by open reduction and internal plate-fixation (Philos, Synthes) or by intramedullary nailing (T2 PHN, Stryker). Until now there have been no randomized controlled trials to proof one of these methods to be superior. The goal of this trial is to point out the surgical intervention with the best functional outcome, measured in Constant-Murley score after 1 year.

Study objective

Intramedullary nailing with the T2 proximal humerus nail results in higher Constant-Murley Score after 1 year compared with open reduction and internal fixation with the Philos plate.

Study design

2 weeks, 6 weeks, 3 months, 6 months, 1 year and 2 year after surgery

Intervention

Patients with a 3-part displaced proximal humeral fracture have an indication for surgical treatment. Until now there is no superior technique. Therefore patients will be randomized for osteosynthesis using the Philos plate (Proximal humeral internal locking system, Synthes) or PHN (Proximal Humeral Nailing system, Stryker).

The primary outcome is the Constant-Murley score after 1 year of follow-up. This is the recommended score to express schoulder function. The intervention is the only difference between the 2 groups. Follow-up duration and schedule is similar.

Contacts

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Eligibility criteria

Inclusion criteria

1. Adult men and women aged 18 years or older;

2. Unilateral acute dislocated three-part proximal humeral fracture (>45 degrees of angulation or > 0,5 cm of dislocation between major fracture fragments);

3. Fit for surgery;

4. Operative treatment within 21 days post-fracture;

5. Provision of informed consent by patient.

Exclusion criteria

1. bilateral proximal humeral fractures;

2. other major trauma / fractures;

3. pathological, recurrent or open fractures;

4. pre-existing impaired shoulder function (i.e., stiff or painful shoulder, neurologic disorder of the upper limb, or diagnosed rotator cuff impairment;

5. Retained hardware around the affected humerus;

6. a disorder of bone metabolism other than osteoporosis (i.e., Paget’s disease, renal osteodystrophy, osteomalacia);

7. Moderate or severe cognitively impaired patients (i.e., Mini-Mental Status Examination (MMSE) Six Item Screener with 3 or more errors);

8. Likely problems, in the judgment of the investigators, with maintaining follow-up (e.g., patients with no fixed address will be excluded);

9. Insufficient comprehension of the Dutch language to understand a rehabilitation program and other treatment information in the judgment of the attending physician;

10. Patients with follow-up in other then the participating hospitals.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2013
Enrollment:	92
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 43697
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3859
NTR-old	NTR4019
CCMO	NL40644.068.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON43697

Study results

Summary results
N/A