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

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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.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24602

Bron
NTR

Verkorte titel
PROMOTION-trial

Aandoening

bovenarmbreuk
humerus fracture

Ondersteuning

Primaire sponsor: Maastricht University Medical Center
Overige ondersteuning: Maastricht University Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2013
Aantal proefpersonen:	92
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 43697
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A