Four-part fractures of the proximal humerus; conservative treatment or reversed type shoulder prosthesis

Published: 07-12-2010
Last updated: 02-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint injuries
Study type	Interventional

Summary

ID

NL-OMON34780

Source
ToetsingOnline

Brief title
Delta Xtend reversed shoulder prosthesis

Condition

- Bone and joint injuries
- Joint disorders
- Bone and joint therapeutic procedures

Synonym
Reversed shoulder arthroplasty (after proximal humerus fracture)

Research involving
Human

Sponsors and support

Primary sponsor: Alysis Zorggroep

Source(s) of monetary or material Support: Johnson & Johnson Medical BV, Computerweg 14, 3821 AB, Amersfoort, The Netherlands,Johnson & Johnson Medical BV;Computerweg 14;3821 AB;Amersfoort;The Netherlands

Intervention

Keyword: conservative treatment, four-part fracture, reversed shoulder prosthesis

Outcome measures

Primary outcome

Difference in Constant Murley Score at 12 months between the intervention and historical control group.

Secondary outcome

Constant Murley score at 3 months. Visual analogue scale (VAS) for pain and impairment, range of motion (ROM), MecMesin myometer measurement of abduction force in Newton, and postoperative standing AP, axial and SOV radiographs at 3 and 12 months. Dutch simple shoulder test at 12 months.

Perioperative complications, postoperative complications and adverse events will be counted for type (% of total events) at 12 months.

Study description

Background summary

Displaced four-part fractures are among the most severe injuries and are positively correlated with age and osteoporosis. The optimal treatment for displaced four-part fractures is disputed. Recent systematic reviews [6, 16, 17] emphasised that the limited evidence available does not confirm that surgery (i.e. hemiprosthesis) is preferable to conservative treatment in displaced fractures and concluded that published data are inadequate for

evidence-based decision making. In a few recent studies [18, 19] promising results, in the management of four-part proximal humerus fractures, are mentioned with a reverse prosthesis. To our knowledge, the Delta Xtend reversed shoulder prosthesis has never been compared to conservative treatment in the management of displaced 4-part fractures of the proximal humerus.

Study objective

Our primary objective is to compare the short-term (one-year follow-up) clinical results of the DePuy Delta Xtend reversed shoulder prosthesis with conservative treatment, in the management of displaced four-part fractures of the proximal humerus of elderly.

Study design

Prospective single arm trial (Depuy, Delta Xtend reversed shoulder prosthesis) versus historical control group (conservative treatment).

Intervention

A Delta Xtend reversed shoulder prosthesis will be inserted in all patients. All patients will receive a clinical and post clinical standardised rehabilitation program.

Study burden and risks

The limited evidence available does not confirm that surgery (i.e. hemiprosthesis) is preferable to conservative treatment in displaced fractures. In recent studies promising results are mentioned with a reversed prosthesis. The potential risk of a Delta Xtend prosthesis (reversed shoulder prosthesis) is no different than with a hemiprosthesis, which is a fully accepted treatment of four-part fractures. The extra burden associated with participation in this study are the Constant Murley Score, the MecMesin Myometer abduction force test and the radiographs at 3 and 12 months and the Dutch simple shoulder test at 12 months.

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

* > 70 years of age
* 4-part fracture confirmed by 2 orthopaedic surgeons on X-ray
* Informed consent / patient information
* Mentally alert and physically fit (ASA-group 1-3) for surgery and rehabilitation
* The patient agrees to comply with postoperative clinical and radiographic evaluations and the required rehabilitation regime

Exclusion criteria

* Pathological or complex fracture
* Pathology of the contra lateral shoulder
* Dementia
* Active infection
* Axillary nerve palsy
* A deficient deltoid muscle
* Abuse problems
* Unable to understand the meaning of informed consent, the patient information, instructions in
Dutch and follow the rehabilitation protocol
* The subject has participated in clinical trials evaluating investigational devices,

pharmaceuticals or biologics within 3 months of enrolment in the study

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-02-2011
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO

Date:	07-12-2010
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
Other	Het is aangemeld in het Nederlands Trial Register. We wachten nog op het registratienummer
CCMO	NL30609.091.10