Delta Xtend reversed shoulder prosthesis.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25375

Source
NTR

Brief title
Delta Xtend

Health condition

four-part fracture, conservative treatment, reversed shoulder prosthesis

Sponsors and support

Primary sponsor: Maatschap Orthopaedie Ziekenhuis Rijnstate
Source(s) of monetary or material Support: Johnson & Johnson Medical BV, Computerweg 14, 3821 AB, Amersfoort, The Netherlands

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Constant Murley score at 3 months;

2. Visual analogue scale (VAS) for pain and impairment;

3. Range of motion (ROM);

4. MecMesin myometer measurement of abduction force in Newton;

5. Postoperative standing AP;

6. Axial and SOV radiographs at 3 and 12 months;

7. 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

Background of the study:

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 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 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.

Objective of the study:

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).

Study population:

Patients diagnosed with displaced four-part fracture, > 70 years old.

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.

Primary study parameters/outcome of the study:

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

Secundary study parameters/outcome of the study (if applicable):

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.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

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.

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

Follow-up at 1 week, 6 weeks, 3 months and 12 months.

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.

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

Contacts

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Eligibility criteria

Inclusion criteria

1. > 70 years of age;

2. 4-part fracture confirmed by 2 orthopaedic surgeons on X-ray;

3. Informed consent / patient information;

4. Mentally alert and physically fit (ASA-group 1-3) for surgery and rehabilitation;

5. The patient agrees to comply with postoperative clinical and radiographic evaluations and the required rehabilitation regime.

Exclusion criteria

1. Pathological or complex fracture;

2. Pathology of the contra lateral shoulder;

3. Dementia;

4. Active infection;

5. Axillary nerve palsy;

6. A deficient deltoid muscle;

7. Abuse problems;

8. Unable to understand the meaning of informed consent, the patient information, instructions in
Dutch and follow the rehabilitation protocol ;

9. 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:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2010
Enrollment:	25
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-01-2010
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	NL2069
NTR-old	NTR2186
Other	METC / ABR : 2010/039 / NL30609.091.10 ;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A