ISRCTN28175069 https://doi.org/10.1186/ISRCTN28175069

Placement of shoulder replacement for complex upper arm fractures

Submission date
12/02/2020

Recruitment status
No longer recruiting

Registration date
21/04/2020

Overall study status
Completed

Last Edited
20/04/2020

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The proximal fracture of the humerus (where the upper arm joins the shoulder) is one of the most common fractures in elderly patients. The placement of shoulder prosthesis used for reconstruction of a complex proximal humerus fractures is challenging. To achieve the anatomical placement of prosthesis, the researchers introduced a new operative technique to determine the humerus height and humeral head retroversion. Herein, the researchers retrospectively investigated the clinical and radiographic outcomes of our procedure

Who can participate?
Patients treated by shoulder arthroplasty for proximal humeral fracture during the period between June 2016 and December 2018.

What does the study involve?
34 patients, treated by shoulder arthroplasty for 4-part or 3–part proximal humeral fracture during the period between June 2016 and December 2018, were enrolled in the study. Patients treated with classic method were compared to patients treated with the new method treated patients by operation time, blood loss, pain, range of motion, Constant-Murley score and radiologic features.

What are the possible benefits and risks of participating?
None (retrospective study).

Where is the study run from?
Tianjin Hospital (China)

When is the study starting and how long is it expected to run for?
June 2016 to December 2018

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Anatomic placement of shoulder prosthesis for complex proximal humerus fractures

Study objectives
The placement of shoulder prosthesis used for reconstruction of a complex proximal humerus fractures is challenging. To achieve the anatomical placement of prosthesis, we introduced a new operative technique to determine the humerus height and humeral head retroversion. Herein, we retrospectively investigated the clinical and radiographic outcomes of our procedure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/03/2020, Ethics committee of Tianjin Hospital (Jiefang Rd. 406, TianJin, China, 300202; +86 (0)22-60910673), ref: daibincn@sina.com

Study design
Retrospective observational study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Proximal fracture of humerus

Interventions
The patients were treated with classic method during the period between June 2016 and August 2017. The surgeons involved in this study stopped using this method and switched to our modified method from September 2017 to December 2018. Herein, we retrospectively investigated the clinical and radiographic outcomes of the two procedures. The total duration of follow-up was set as the period between operation and last follow-up.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Overall shoulder function measure using the constant-Murley score at the last follow up appointment

Key secondary outcome(s))
1. Shoulder pain measured using Visual Analog scale at follow up appointments
2. ROM of shoulder measured at follow up appointments
3. Radiologic outcomes (anteroposterior, scapular Y, and axillary views, and the status of tuberosities is defined as healing, malunion, migration, and resorption) measured at follow up appointments

Completion date
01/10/2020

Eligibility

Key inclusion criteria
Patients treated by shoulder arthroplasty for proximal humeral fracture during the period between June 2016 and December 2018

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
34

Key exclusion criteria
The patients can not be followed up.

Date of first enrolment
01/06/2016

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
China

Study participating centre
Tianjin Hospital
Jie Fang Rd. 406
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Sponsor information

Organisation
Tianjin Hospital

Funder(s)

Funder type

Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes