

Placement of shoulder replacement for complex upper arm fractures

Submission date 12/02/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 21/04/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 20/04/2020	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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?

Jian'an Li

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Nested case-control study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

No participant information sheet available

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 measure

Overall shoulder function measure using the constant-Murley score at the last follow up appointment

Secondary outcome measures

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

Overall study start date

01/10/2019

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

34

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

Tianjin
China
300211

Sponsor information

Organisation

Tianjin Hospital

Sponsor details

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Sponsor type

Hospital/treatment centre

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

BMC musculoskeletal disorders.

Intention to publish date

31/03/2020

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

