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Comparing the outcomes of non-surgical versus surgical treatment of shoulder fractures with different shoulder replacements

Submission date	Recruitment status	[X] Prospectively registered
03/07/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
08/07/2021	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
30/12/2024	Injury, Occupational Diseases, Poisoning	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The optimal treatment of complex shoulder fracture is controversial. In general, non-surgical treatment is recommended for older patients, but results are often unsatisfying. Therefore different surgical approaches have been tried to improve outcomes for this group of patients. Reverse shoulder arthroplasty has shown promising results for these types of fractures and changes in the design of the implant might improve outcomes further. The aim of this study is to compare the outcomes of complex shoulder fractures after non-surgical versus surgical treatment and compare two different types of implants.

Who can participate?
Patients aged above 60 years with complex shoulder fractures

What does the study involve?
Participants are randomly allocated to one of three groups:
Group 1: non-surgical treatment (rehabilitation only)
Group 2: surgical replacement with a 155-degree inclination angle
Group 3: surgical replacement with a 135-degree inclination angle
Participants are followed up after 3, 12 and 24 months. All groups also receive a similar standard rehabilitation program. They have to fill in on questionnaires and measurements of their range of movement and strength will be taken, as well as x-rays.

What are the possible benefits and risks of participating?
There is neither a definite benefit nor risk of participating. All patients who meet the inclusion criteria will be offered the same treatment non-surgical or surgical options, even if they choose not to participate in this study. The treatments are common procedures, the only difference is patients can't choose the treatment.

Where is the study run from?
Hospital South West Jutland (Denmark)

When is the study starting and how long is it expected to run for?
April 2021 to September 2027

Who is funding the study?
Hospital South West Jutland (Denmark)

Who is the main contact?
Dr Klaus Hanisch
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Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT06444828

Protocol serial number
IRSTA 123456

Study information

Scientific Title
Outcome following reverse shoulder arthroplasty for acute proximal humerus fractures with different humerus inclination angles versus non-surgical treatment

Study objectives
The aim of the study is to compare the outcomes of different designed reverse shoulder arthroplasty (RSA) versus conservative treatment of proximal humeral fracture (PHF) Neer type III or IV / AO B2, C2.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 01/09/2021, the scientific ethic committee of the region south Denmark (De Videnskabsetiske Komite, Regionshuset, Damhaven 12, 7100, Vejle, Denmark; +45 (0)76638221, +45 (0)29201203; komite@rsyd.dk), ref: 82397

Primary study design
Interventional

Study design
Randomized single-blinded controlled study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Proximal humeral fracture type Neer 3 & 4

Interventions
90 patients are randomized to one of three groups:
Group 1: non-surgical treatment (rehabilitation only)
Group 2: surgical replacement with a 155-degree inclination angle
Group 3: surgical replacement with a 135-degree inclination angle

Participants are followed up at 3, 12 and 24 months.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Measured at 3, 12 and 24 months:
1. Quality of life measured using the Western Ontario Osteoarthritis score (WOOS)
2. Pain, activities of daily living, range of movement and strength measured by specially trained physiotherapists with the Constant Murley (CS) score
3. Quality of life measured using the Subjective Shoulder Value (SSV) questionnaire
4. Bone healing response evaluated using x-ray as union/non-union/pseudarthrosis in the non-surgical group and status of healing of the tuberosities as healed, displaced over 5 mm or resorbed

Key secondary outcome(s)
Complications and revisions reported in medical records within the 2 years of follow up

Completion date
01/09/2027

Eligibility

Key inclusion criteria

1. Proximal humerus fracture type Neer 3 & 4
2. Older than 60 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
60 Years

Sex
All

Key exclusion criteria
1. Age younger than 60 years
2. Conditions where surgery is mandatory
3. Patients who can't answer questions because of the effects of dementia

Date of first enrolment
01/09/2021

Date of final enrolment
01/09/2025

Locations

Countries of recruitment
Denmark

Study participating centre
Hospital South West Jutland
Finsensgade 35
Esbjerg
Denmark
6700

Sponsor information

Organisation

Hospital South West Jutland

ROR
https://ror.org/03pzgk858

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hospital South West Jutland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Klaus Hanisch (klaus.hanisch@rsyd.dk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		09/10/2024	30/12/2024	Yes	No
Participant information sheet			04/08/2021	No	Yes
Protocol file			04/08/2021	No	No