

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

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<b>Registration date</b> 08/07/2021	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 30/12/2024	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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  
klaus.hanisch@rsyd.dk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**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 Videnskabssetiske Komite, Regionshuset, Damhaven 12, 7100, Vejle, Denmark; +45 (0)76638221, +45 (0)29201203; komite@rsyd.dk), ref: 82397

### **Study design**

Randomized single-blinded controlled study

### **Primary study design**

Interventional

### **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](mailto:klaus.hanisch@rsyd.dk)).

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	Participant information sheet	09/10/2024	30/12/2024	Yes	No
<a href="#">Participant information sheet</a>			04/08/2021	No	Yes
<a href="#">Participant information sheet</a>		11/11/2025	11/11/2025	No	Yes
<a href="#">Protocol file</a>			04/08/2021	No	No