

The effect of custom-made 3-D printed guides in total shoulder joint replacement

Submission date 29/09/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/10/2020	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 01/02/2022	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 shoulder is a ball and socket-type joint made up of two main parts: the glenoid (socket) and the humerus (upper arm bone, which makes up the ball). It is therefore known as the glenohumeral joint. When arthritis affects the shoulder it causes the lining of these joint surfaces to wear, causing pain and stiffness. During a total shoulder replacement (arthroplasty), both the head of the humerus and the socket are replaced with artificial surfaces (metal and plastic). Reducing operation time and being more precise in the insertion of the arthroplasty should in theory provide better outcomes and fewer failures. The aim of this study is to assess the effect of the use of three-D printed custom-made guides for the placement of the glenoid part of the arthroplasty.

Who can participate?

Patients receiving an offer of a shoulder arthroplasty to treat their shoulder osteoarthritis will be asked to participate in the study.

What does the study involve?

Participants will be randomly allocated to receive shoulder replacement with or without the use of a custom made guide.

What are the possible benefits and risks of participating?

Benefits could be better movement of the shoulder, better placement and longer survival of the arthroplasty.

The use of "custom-made guides" for operation is not in any way expected to introduce new risk or aggravate the already existing risks of a shoulder arthroplasty operation.

Where is the study run from?

Orthopedic Department, University Hospital of Southwest Jutland (Denmark)

When is the study starting and how long is it expected to run for?

October 2019 to December 2023

Who is funding the study?

1. Innovation foundation of the Region of South Denmark
2. Orthopedic Department, University Hospital of Southwest Jutland, Denmark

Who is the main contact?

Prof. Niels Wedderkopp, nwedderkopp@health.sdu.dk

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

75988

Study information

Scientific Title

The effect of custom-made 3-D printed guides for insertion of the glenoid part in total shoulder arthroplasty. A prospective randomized study

Study objectives

To assess the effect of the use of 3D printed custom-made guides for the placement of the glenoid part of the arthroplasty. A custom-made guide should 1. Shorten the operating time, 2. Make the placement more precise, and through these improvements make the patient less prone to complications like infections and dislocations.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 21/01/2021, Ethics committee of South Denmark (Regionshuset, Damhaven 12, 7100 Vejle, Denmark; no telephone number provided; komite@rsyd.dk), ref: S-20200163

Study design

Single-center double-blind randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Shoulder osteoarthritis

Interventions

The participants will be randomly put into two groups (block randomization with four subjects in each block using STATA 16 MP):

The intervention group will have 3D printed custom-made guides used for the placement of the glenoid part of shoulder arthroplasty.

The control group will have the traditional surgery without custom made guide.

The two groups will followed-up using Patient Reported Outcome Measures (PROMs) and CT-scans. The PROMs will be administered at baseline, and at 3,6 and 12 months postoperatively. In addition, the patients will be followed with "momentary assessment" questionnaires every week to assess the trajectories of the rehabilitation.

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. Self-reported shoulder function measured using The Western Ontario Osteoarthritis of the Shoulder index at baseline, 3, 6, 12 and 24 months follow-up
2. Level of activity measured using the Constant-Murley score (by a physiotherapist) at baseline, 3, 6, 12 and 24 months follow-up
3. Self-reported pain level using numeric rating scale reported weekly by SMS

Key secondary outcome(s))

Placement of the arthroplasty assessed using a CT-scan at 12 months

Completion date

31/12/2023

Reason abandoned (if study stopped)

Lack of staff/facilities/resources

Eligibility

Key inclusion criteria

Shoulder osteoarthritis patients that will receive a shoulder arthroplasty

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Hypoplasia
2. Severe osteoarthritis requiring a custom made guide under all circumstances

Date of first enrolment

14/06/2021

Date of final enrolment

31/12/2021

Locations

Countries of recruitment

Denmark

Study participating centre

University Hospital of Southwest Jutland

Orthopedic department

Finsensgade 35

Esbjerg

Denmark

6700

Sponsor information

Organisation

University of Southern Denmark

ROR

<https://ror.org/03yrrjy16>

Funder(s)**Funder type**

Government

Funder Name

Innovation foundation of the Region of South Denmark

Funder Name

Orthopedic dep. University Hospital of Southwest Jutland, Denmark.

Results and Publications**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary

Available on request