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

Submission date
29/09/2020

Recruitment status
No longer recruiting

Registration date
28/10/2020

Overall study status
Stopped

Last Edited
01/02/2022

Condition category
Musculoskeletal Diseases

[X] 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 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 gleno-humeral 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web-format, please use contact details to request a participant information sheet.

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 measure

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

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

Overall study start date
01/10/2019

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

Age group
Adult

Sex
Both

Target number of participants
118

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
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Sponsor information

Organisation
University of Southern Denmark

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Sponsor type
University/education

Website
https://www.sdu.dk/en/om_sdu/institutter_centre/irs_regional_sundhedsforskning

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

Publication and dissemination plan
Plan to publish the results in The Journal of Shoulder and Elbow Surgery.

Intention to publish date
01/06/2024

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