Long Term Follow-up after Primary or Revision Shoulder Arthroplasty with a Patient- specific Glenius Implant: A prospective case series

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Observational invasive

Summary

ID

NL-OMON55667

Source
ToetsingOnline

Brief title
Glenius study

Condition

- Joint disorders

Synonym
osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Materialise NV

Source(s) of monetary or material Support: Materialise NV

Intervention

Keyword: Patient-specific prothesis, Reversed total shoulder arthroplasty, Shoulder Osteoarthritis

Outcome measures

Primary outcome

• Clinical outcome will measured with Constant-Murley Score before surgery and at each follow-up visit. One and 5-year follow-up score will be compared to the pre-surgery score.

Secondary outcome

• Patient reported clinical outcome measures (PROMS) will be collected through Simple Shoulder Test (SST), Oxford ShoulderScore, general health EQ5D and pain and satisfaction scores via Visual Analogue Scales (VAS) before surgery and at each visit.

• The accuracy of implant position will be measured by calculating positional and rotational deviations of the implant position onpost-operative CT scan when compared to the planned position on the pre-operative CT scan.

• Implant stability will be assessed by calculating translational and rotational deviations on a CT scan 1 year after surgery, comparedto the position on the post-operative CT scan.

• Other radiological outcomes will be identified and graded on the X-rays: scapular notching, radiolucencies and heterotopicossification after surgery at each follow-up visit.

• Implant survival will be calculated by collecting dates of implant revision

surgeries.

• Collecting (severe) adverse (device) events: device/shoulder related A(D)Es,

SA(D)Es and device deficiencies that could have led to an SAE will be

collected.

Study description

Background summary

The Glenius Glenoid Reconstruction system provides a patient-specific solution for the treatment of glenoid defects in reversed total shoulder arthroplasty (rTSA). Better understanding of clinical outcome may improve the success of surgery and implants leading to reduced (re-)revision rates. Counselling of patients and surgical planning may be improved. Furthermore, clinical outcome data on specific surgical techniques and implants is useful from a general health economics perspective, and more specific to support reimbursement and insurance requests . Therefore, the current study protocol on primary and revision shoulder arthroplasty outcome with Glenius was set up to gather clinical follow-up data in a standardized way.

Study objective

The primary objective of this study is to assess the improvement in clinical outcome of rTSA with Glenius one year after surgery. The secondary objectives are to gather patient-reported clinical outcomes, radiological outcomes (implant position/migration, complications), implant revision rates and safety up to 5 years after surgery.

Study design

The study is designed as a prospective interventional case series study with a follow-up of 5 years. No case control group is included.

Study burden and risks

Patients participating in this study will not be subjected to any additional risk other than the regular risks for rTSA, compared to patients receiving treatment outside the study. Only the additional post-op CT scan(s) 1 year after surgery will pose an additional radiation risk of 2.1 mSv, which is lower than one year of natural background radiation (2.5 mSv). The patients will visit the clinic at regular follow-up moments including standard physical

examinations and radiographic assessments. The patients will be asked to fill out the questionnaires prior to the clinical examination visit, which will take a few minutes (15min) of their time.

Contacts

Public
Materialise NV

Technologielaan 15
Leuven 3001
BE
Scientific
Materialise NV

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• patients having primary or revision shoulder joint replacement with severe glenoid bone defects caused by: (1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis, (2) Inflammatory degenerative joint disease such as rheumatoid arthritis; (3) Congenital malformations, posttraumatic deformities or removal of components during revision surgery
• Patient is 18 years of age or older
• Patient can follow the Glenius system procedure that is standard of care and

according to the appropriate Glenius system instructions for use.
• Patient has participated in the informed consent process and has signed the EC approved informed consent form

Exclusion criteria

• Pregnant patients
• Skeletally immature patients
• Prisoners

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-08-2020
Enrollment:	14
Type:	Actual

Medical products/devices used

Generic name:	Glenius glenoid reconstruction system
Registration:	No

Ethics review

Approved WMO

Date:	11-09-2019

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-11-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-01-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-01-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT03806881
CCMO	NL64181.091.19