A multicentre, prospective clinical study analysing outcomes of shoulder arthroplasty with SMR STEMLESS

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• Assessment of clinical, radiographic and subjective outcomes after anatomic or reverse shoulder arthroplasty with SMR stemless prosthesis;• Survival analysis;• Incidence of adverse events and identification of possible risk factors for failure.

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

Summary

ID

NL-OMON47760

Source
ToetsingOnline

Brief title
SMR Stemless

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
osteoarthritis of the shoulder; cuff tear arthropathy

Research involving
Human

Sponsors and support

Primary sponsor: NAMSA
Source(s) of monetary or material Support: Limacorporate spa

Intervention

Keyword: Anatomical Shoulder arthroplasty, Reverse Shoulder arthroplasty, SMR Stemless

Outcome measures

Primary outcome

The primary endpoint consist of the proportion of patients reaching a clinical progression from baseline to 24-month follow-up measured as:

• Constant score change of greater than 10;

• Adjusted Constant score greater than or equal to 54.

Secondary outcome

The secondary endpoints are:

• improvement from patient perspective from baseline to 24-month follow-up measured as change of the ASES score, Oxford shoulder score and patient satisfaction;

• stability of the humeral component, intended as rate of symptomatic radiolucent lines, loosening and subsidence >=2 mm, from immediate postoperative (baseline) to 24-month;

• Failure rate, intended as removal of the humeral component, from immediate postoperative (baseline) to 24-month;

• Incidence of device-related AE/SAE (ADE/SADE) from immediate postoperative (baseline) to 24-month.

Study description

Background summary

The SMR Stemless System was developed maintaining the modularity concept of the SMR Shoulder System in order to provide solutions for wide variations of indications encountered in shoulder arthroplasty surgery. It allows to perform anatomic or reverse shoulder arthroplasty using the same SMR Stemless Core which does not need to be replaced in case of revision surgery if it is stable and well osseointegrated.

The hypothesis at the base of the study is that the SMR stemless system might contribute to ensure good clinical outcomes and an effective stability and might avoid the potential complications associated with a traditional stemmed implant.

The aim of this study is to assess clinical, radiographic and subjective outcomes after anatomic or reverse shoulder arthroplasty with a SMR stemless prosthesis, define the survivorship of the implant and identify possible risk factors that may lead to failure.

Study objective

• Assessment of clinical, radiographic and subjective outcomes after anatomic or reverse shoulder arthroplasty with SMR stemless prosthesis;
• Survival analysis;
• Incidence of adverse events and identification of possible risk factors for failure.

Study design

Post-market, prospective, consecutive series, non randomized, open label, internal control

Study burden and risks

Shoulder replacement is the routine treatment following diagnosis of degenerative shoulder disease.
The possible risks and/or discomforts associated with this shoulder replacement operation are identical to those for all standard total shoulder replacement operations and are independent from the decision to participate in this study. The patients will visit the clinic at regular follow-up moments up to one year, and will receive a travel reimbursement for the additional visits. All visits take ±15 min extra than regularly because at these moments the patient visits also the research nurse for data collection. The questionnaires and physical examinations of the shoulder do not bring any extra burden. The additional radiographic assessments increase the total amount of radiation only slightly. However, the total amount of radiation falls within the limits for medical

research.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Patient is requiring primary unilateral or bilateral anatomic or reverse arthroplasty based on physical examination and medical history;
- Good bone quality evaluated by the Investigator on the basis of a risk factors analysis (included MORES/SCORE questionnaires) and the intraoperative evaluation;
- A diagnosis in the target shoulder of one or more of the following:
• Primary osteoarthritis;
• Secondary osteoarthritis;
• Post-traumatic arthritis;

• Rheumatoid arthritis;
• Avascular necrosis of the humeral head (radiologically less than 20%);
• Cuff tear arthropathy.
- Patient submitted to previous conservative non-surgical treatments;
- Patient is willing and able to complete scheduled follow-up evaluations as described in the Informed Consent;
- Patient has participated in the Informed Consent process and has signed the Informed Consent form previously approved by the Ethics Committee.

Exclusion criteria

- Patient requiring revision shoulder arthroplasty;
- Osteoporosis with a history of non-traumatic fractures;
- Steroid injections within the previous 3 months;
- Contralateral shoulder replacement within the previous 3 months;
- Extensive avascular necrosis (radiologically more than 20%);
- Meta-epiphyseal bony defect (including large cysts);
- Post-traumatic tuberosity non-union;
- Ongoing septicaemia;
- Significant proven or suspicious infection of the target shoulder or any serious infectious disease before the study according to the Investigator;
- Significant neurological or musculoskeletal disorders that may compromise functional recovery;
- Not recovered axillary nerve palsy;
- Non functioning deltoid muscle;
- Known or suspicious hypersensitivity to the metal or other components and materials of the implant;
- Recurrent medical history of immune-mediated reactions or other systemic immune disorders;
- Current treatment or treatment for any malignancy within the previous 2 years before the preoperative visit;
- Previous organ transplant;
- Women of childbearing potential who are pregnant, nursing, or planning to become pregnant.

Study design

Design

Study type: Observational invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-03-2016
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	SMR Stemless
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	16-12-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-05-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-05-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-04-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL54378.094.15