Deltoid volume and strength following reverse shoulder arthroplasty

Published: 06-05-2019
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Determing the relation between postoperative deltoid volume and clinical outcome following reversed shoulder arthroplasty after 2-13 years of followup.

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

Summary

ID

NL-OMON48441

Source
ToetsingOnline

Brief title
deltoid volume

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
glenohumeral arthritis, shoulder osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: HagaZiekenhuis
Source(s) of monetary or material Support: HagaZiekenhuis

Intervention

Keyword: Cuff arthropathy, Reversed shoulder, Shoulder arthroplasty

Outcome measures

Primary outcome

Relation in postoperative change in deltoid volume and Constant Murley score

Secondary outcome

Oxford Shoulder score, range of motion (abduction, anteflexion, glenohumeral abduction, external rotation, internal rotation, abduction+external rotation), relation in postoperative change in deltoid volume and change in distalisation of the humeral head.

Study description

Background summary

Remain of a proper function and strength of the deltoid muscle is an important theoretical factor in long term results after reversed shoulder arthroplasty. Because of the changed - non-anatomical - biomechanical situation following reversed arthroplasty, there are doubts about the resistency of the deltoid muscle against this changed situation. We hypothesize that a postoperative decrease in volume of the deltoid muscle has a negative effect on clinical outcome scores.

Study objective

Determing the relation between postoperative deltoid volume and clinical outcome following reversed shoulder arthroplasty after 2-13 years of followup.

Study design

The study design is observational.

Study burden and risks

There is no different treatment. In addition to standard care there will be one extra outpatient clinic meeting where we measure Range of Motion and deltoid strength and complete two short questionnaires on the function of the operated shoulder. Those questionnairs are completed pre-operatively as part of standard care.
Further we will perform ultrasound measurement of the deltoid muscle on the operated and healthy shoulder.

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

Reversed shoulder prosthesis placed in our hospital between 01-01-2006 and 01-01-2017.

Exclusion criteria

- Age below 18 years
- No comprehension of Dutch language
- Revision- or fracture prosthesis

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-11-2019
Enrollment:	102
Type:	Actual

Ethics review

Approved WMO

Date:	06-05-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	20-08-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL69017.098.19

Study results

Date completed: 17-01-2020

Summary results
Trial ended prematurely