

Conform and non conform glenoid components in total shoulder replacements

Submission date 28/12/2006	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 28/12/2006	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 28/12/2006	Condition category Musculoskeletal Diseases	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
p06.017

Study information

Scientific Title

Study objectives

Conform components are beneficial for motion coordination and reducing high rim-loads, while non-conform components are beneficial in reducing high humerus-to-scapula impulses (impact forces).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Primary study design

Interventional

Study design

Randomised, controlled, parallel group, double blinded trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Shoulder disorders

Interventions

Total shoulder replacement

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Component fixation (Rontgen Stereophotographic Analysis [RSA])
2. Shoulder functioning (Range of Motion [RoM], Questionnaires for shoulder functioning)

Key secondary outcome(s)

1. Glenohumeral translation (Fluoroscopy)
2. Pain (Visual Analogue Scale [VAS])
3. Maximum arm force
4. Shoulder coordination (Principal action)
5. Proprioception (mirroring)

Completion date

01/11/2010

Eligibility**Key inclusion criteria**

Individuals requiring primary arthroplasty as a result of osteoarthritis or rheumatoid arthritis.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

1. Rotator cuff tear, pre-operatively diagnosed by means of Magnetic Resonance Imaging (MRI)
2. Humeral component with a radius of 20 mm
3. Prior history of shoulder surgery

Date of first enrolment

01/11/2006

Date of final enrolment

01/11/2010

Locations**Countries of recruitment**

Netherlands

Study participating centre

Leiden University Medical Center

Leiden

Netherlands

2300 RC

Sponsor information**Organisation**

Leiden University Medical Center (LUMC) (The Netherlands)

ROR

<https://ror.org/05xvt9f17>

Funder(s)

Funder type

Industry

Funder Name

Reumafonds (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration