

Conform and non conform glenoid components in total shoulder replacements

Submission date 28/12/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/12/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 28/12/2006	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design

Randomised, controlled, parallel group, double blinded trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Shoulder disorders

Interventions

Total shoulder replacement

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

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

Secondary outcome measures

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

Overall study start date

01/11/2006

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

Age group

Not Specified

Sex

Not Specified

Target number of participants

20

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)

Sponsor details

Department of Orthopaedics
Laboratory for Movement Analysis
P.O. Box 9600
Leiden
Netherlands
2300 RC

Sponsor type

Hospital/treatment centre

Website

http://www.lumc.nl/english/start_english.html#http://www.lumc.nl/english/start_english.html

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Reumafonds (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration