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Conform and non conform glenoid components in total shoulder replacements

Submission date	Recruitment status	[ ] Prospectively registered
28/12/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/12/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/12/2006	Musculoskeletal Diseases	[ ] 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. Proprosepsis (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
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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