# Conform and non conform glenoid components in total shoulder replacements

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
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

#### Contact name

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#### Contact details

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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

#### Study design

Randomised, controlled, parallel group, double blinded trial

#### Primary study design

Interventional

#### 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. Proprosepsis (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