Conform and non conform glenoid components in total shoulder replacements.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25932

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Patients requiring total shoulder replacement

Sponsors and support

Primary sponsor: Laboratory for Movement Analysis
Leiden University Medical Center
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Source(s) of monetary or material Support: Reumafonds

Intervention

Outcome measures

Primary outcome

1. Component fixation (Rontgen Stereophotographic Analysis (RSA))

2. Shoulderfunctioning (Range of Motion (RoM), Questionnaires for shoulder functioning)

Secondary outcome

1. Glenohumeral translation (Fluoroscopy)

2. Pain (VAS)

3. Maximum arm force

4. Shoulder coordination (Principal action)

5. Proprosepsis (mirroring)

Study description

Background summary

In this project we will determine the effect of conform and non-conform glenohumeral components in shoulder arthroplasty on glenohumeral fixation and functional outcome. We believe that 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).
Glenoid fixation will be determined by means of Röntgen Stereophotogrammetry Analysis (RSA). Functional outcome will be determined by means of RoM, VAS, MVC and Constant Scores. Patients' level of activity will be determined by means of the Shoulder Rating Questionnaire.
In order to understand the clinical and functional outcome, fluoroscopy will be applied to determine the humerus-to-scapula contact area (i.e. direction of loading of the glenoid component), EMG will be used to determine the Principal Action of the recorded shoulder muscles (measure for coordination and co-contraction), and a shoulder model will be used to simulate the observed conditions in order to predict the effect on muscle forces and consequently, on the loading of the implant components.

Study objective

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).

Intervention

Total shoulder replacement

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

1. Rotator cuff tear, pre-operatively diagnosed by means of MRI.

2. Humeral component with a radius of 20 mm.

3. Prior history of shoulder surgery

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2006
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	21-09-2006
Application type:	First submission

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
NTR-new	NL803
NTR-old	NTR816
Other	: p06.017
ISRCTN	ISRCTN42881741

Study results

Summary results
N/A