Conform and non conform glenoid components in total shoulder replacements.

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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).

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25932

Bron
NTR

Verkorte titel
N/A

Aandoening

Patients requiring total shoulder replacement

Ondersteuning

Primaire sponsor: Laboratory for Movement Analysis
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Overige ondersteuning: Reumafonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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).

Onderzoeksproduct en/of interventie

Total shoulder replacement

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-11-2006
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	21-09-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL803
NTR-old	NTR816
Ander register	: p06.017
ISRCTN	ISRCTN42881741

Resultaten

Samenvatting resultaten
N/A