Radiostereometric analysis as early predictor for aseptic loosening of the femoral component in total hip arthroplasty: A double meta-analysis.

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Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21057

Bron
NTR

Aandoening

Hip, Arthroplasty , Radio Stereometric Analysis, Aseptic loosening, Migration, Clinical introduction, Femoral component

Ondersteuning

Primaire sponsor: Leiden University Medical Center (LUMC), Department of Orthopaedics
Overige ondersteuning: Atlantic Innovation Fund (Atlantic Canada Opportunities Agency)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

RSA studies:
Migration expressed in subsidence, retroversion or Maximal Total Point Motion (MTPM) in the first 2 post-operative years in mm.

Survival / cohort studies:
Percentage revision or intended revision for aseptic loosening of the femoral component at 5 year intervals (e.g. 5 year; 10 year; 15 year et cetera).

Toelichting onderzoek

Achtergrond van het onderzoek

This meta-analysis combines early migration from RSA studies with long term revision rates from survival studies for aseptic loosening of the femoral component. Included RSA studies will be matched to included survival studies according to prosthesis and fixation. Scatter-plots and meta-regression will be used in a sensitivity analysis to evaluate the effect of differences in patient demographics between studies as well as the effect of study quality.

According to the Swedish Hip Registry and Australian National Joint Replacement Registry the standard for revision will be set at 3% at 5 years and 5% at 10 years. These standards will be used to determine the migration thresholds (in mm) for the categories: acceptable, at risk and unacceptable.

Doel van het onderzoek

The aim of the meta-analysis is to investigate the early predictive value of migration measured by RSA 1 year post-operatively for revision for aseptic loosening of the femoral component in THA and to compose migration thresholds for safe and efficient clinical introduction of new designs.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

This is a systematic review and meta-analysis of migration studies (RSA) and survival / cohort studies (revisions for aseptic loosening) of the femoral components in primary total hip arthroplasty (THA).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

RSA studies:

1. Primary Total Hip replacement;

2. Minimal RSA follow-up of 1 year, measuring femoral component migration.

Survival / cohort studies:

1. Primary Total Hip Replacement;

2. Follow up of 5, 10, 15, 20 or 25 years;

3. Endpoint aseptic loosening of femoral component:

A. For which revision surgery was undertaken;

B. For which revision surgery was indicated, but could not be undertaken (patient decline,

poor general health).

4. Survival analysis or % revised due to aseptic loosening on total:

A. Available for specific prosthetic design and fixation;

B. At specific follow up (see point 2).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

RSA studies:

1. Non-clinical studies: Animal, experimental set up, phantom.

Survival / cohort studies:

1. Less than 75 arthroplasties at baseline.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-12-2009
Aantal proefpersonen:	0
Type:	Werkelijke startdatum

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

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	NL2981
NTR-old	NTR3129
Ander register	UTN : U1111-1112-9515
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A