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

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Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26815

Bron
NTR

Aandoening

knee, arthroplasty, tibial component, aseptic loosening, migration, clinical introduction, Radiostereometric analysis (RSA)

Ondersteuning

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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

RSA studies:
Migration expressed in Maximal Total Point Motion (MTPM) at 1 year in mm.

Survival / cohort studies:
Percentage revision or intended revision for aseptic loosening of the tibial 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 tibial component.
Included RSA studies will be matched to included survival studies according to prosthesis, fixation and insert. 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 Swedisch Knee 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 tressholds (in mm) for the categories: acceptable, at risk and unacceptable.

Doel van het onderzoek

The aim of the meta-analysis is to further investigate the early predictive value of migration measured by RSA 1 year post-operatively for revision for aseptic loosening in TKA 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 tibial component in primary total knee arthroplasty (TKA).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

RSA studies:

1. Primary Total Knee replacement;

2. Minimal RSA follow-up of 1 year, measuring prosthesis micromotion.

Survival / cohort studies:

1. Primary Total Knee Replacement;

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

3. Endpoint aseptic loosening of tibial:

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. Minimal 75 arthroplasties at baseline.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-12-2008
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	NL2311
NTR-old	NTR2417
Ander register	UTN : U1111-1112-9513
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A