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

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26815

Source
NTR

Health condition

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

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC); Department of Orthopaedics
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Intervention

Outcome measures

Primary outcome

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).

Secondary outcome

N/A

Study description

Background summary

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.

Study objective

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.

Study design

N/A

Intervention

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).

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Eligibility criteria

Inclusion criteria

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).

Exclusion criteria

RSA studies:

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

Survival / cohort studies:

1. Minimal 75 arthroplasties at baseline.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2008
Enrollment:	0
Type:	Actual

Ethics review

Not applicable
Application type: Not applicable

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	NL2311
NTR-old	NTR2417
Other	UTN : U1111-1112-9513
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A