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

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21057

Source
NTR

Health condition

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

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC), Department of Orthopaedics
Source(s) of monetary or material Support: Atlantic Innovation Fund (Atlantic Canada Opportunities Agency)

Intervention

Outcome measures

Primary outcome

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).

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 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.

Study objective

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.

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 femoral components in primary total hip arthroplasty (THA).

Contacts

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Eligibility criteria

Inclusion criteria

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).

Exclusion criteria

RSA studies:

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

Survival / cohort studies:

1. Less than 75 arthroplasties at baseline.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2009
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	NL2981
NTR-old	NTR3129
Other	UTN : U1111-1112-9515
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A