Migration of the NexGen Total Knee Prosthesis: A 4-arm RCT comparing.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23837

Source
Nationaal Trial Register

Health condition

Knee replacement for painful primary or secondary osteoarthritis

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Leids Universitair Medisch Centrum

Intervention

Outcome measures

Primary outcome

RSA migration during the first 5 years of follow-up.

Secondary outcome

Function, Knee Society Score, Complications.

Study description

Background summary

Before widespread introduction to the market, new prosthesis designs or related developments, the intitial performance should be evaluated using Roentgen Stereophotogrammetric Analysis (RSA). This highly accurate measurement technique determines the initial migration, and thus fixation, of prostheses, which has been shown to be predictive of long-term survivorship. This study is a 4-arm randomized controlled trial which compares the clinical outcome and migration (RSA) of a conventional NexGen Total Knee Posthesis (TKP) with the newly introduced high-flex NexGen TKP, both designs have either a mobile or fixed bearing.

Study objective

Two year migration is comparable between all 4 groups.

Study design

3, 6 and 12 months, annually thereafter.

Intervention

Knee replacement with either a high-flex or conventional NexGen total knee prosthesis with either a fixed or mobile bearing.

Contacts

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Eligibility criteria

Inclusion criteria

All suitable candidates for a Total Knee Replacement who are willing to participate in the study and follow-up.

Exclusion criteria

1. Refusal to participate;

2. Other indications than osteoarhtritis as a reason for knee replacement.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2002
Enrollment:	60
Type:	Actual

Ethics review

Positive opinion

Date:	14-02-2012
Application type:	First submission

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	NL3143
NTR-old	NTR3287
Other	METC LUMC : p04.288
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A