A randomised clinical trial comparing minimal invasive (MIS) total knee replacement (TKR) with conventional total knee replacement

Published: 30-05-2007
Last updated: 11-05-2024

Objective: Does minimal invasive total knee replacement has (at least) comparable or better results to conventional total knee replacement if looked at functional recovery, complications and pain.Amendement 1: measure the accuracy of the cementing...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON35423

Source
ToetsingOnline

Brief title
MIS versus conventional TKR

Condition

- Bone and joint therapeutic procedures

Synonym
osteoarthrosis, worn out knee

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Functional outcome, Minimal invasive surgery, RCT, Total knee replacement

Outcome measures

Primary outcome

Main study parameters/endpoints: Outcome will be clinically measured using the

Knee Society Score (KSS), Oxford knee score, SF-12, KOOS questionnaire, whilst

radiographic outcomes will be evaluated through standard radiographic

parameters. Discharge criteria will be checked at day 3 p.o.

Amendement 1: Penetration dept and wide of bone cement

Secondary outcome

Hb level day 3

Walking stairs (one level)

Transfers

Pain VAS / medication

cement penetration research

Study description

Background summary

Rationale: Minimally invasive total hip and knee arthroplasty have increased enormous in popularity during the last decade, however substantial controversy exist in the orthopaedic community. For surgery like laparoscopic colorectal resection, appendicitis, splenectomy and inguinal hernia repair1-4

meta-analyses have been published showing that despite longer operative times, scopic surgery has advantages like faster recovery and shorter average length of hospital stay. But does the minimal invasive approach in total knee replacement has advantages? Or do we compromise excellent long-term results?

Amendement 1: Concerning the quality of the cementing technique in total knee arthroplasty is little known. Does the MIS approach have an influence on this cementing technique?

Study objective

Objective: Does minimal invasive total knee replacement has (at least) comparable or better results to conventional total knee replacement if looked at functional recovery, complications and pain.

Amendement 1: measure the accuracy of the cementing technique

Study design

Study design: A prospective randomised clinical trial in which 100 cases will be enrolled.
Patients will be evaluated preoperatively, and postoperatively at discharge (from operation date to date of discharge), at 6 weeks, at 3 months, 1 year.

Amendement 1: patients will be asked to have one CT scan (diagnostic)

Intervention

Intervention: Placement of an cemented primary total knee replacement with a conventional incision or with a minimal invasive approach.

Amendement 1: CT scan

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients participating in the study have the same risks and benefits when not participating in the study. The minimal invasive approach is possible through the new instrumentation, which is also used in the conventional approach. Follow-up times are standard protocol evaluations of prosthesis. Besides standard radiologic follow-up, patients are evaluated with routine questionnaires.

Amendement 1: CT scan has acceptable radiation properties, well below the annual threshold

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

osteoarthrosis

Exclusion criteria

unwilling to participate

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-08-2007
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	30-05-2007
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	30-07-2010
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
CCMO	NL14807.098.06