Determining realistic prognosis of outcome of total knee arthroplasty

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Answer the following questions:1. What are the long term results (>20y) of patients with a primary total knee prosthesis (type Total Condylar) for different endpoints:a. Removal of the prosthesis. (with or without re-implantation)b. Recommended...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON34734

Source
ToetsingOnline

Brief title
Determining realistic prognosis of outcome of total knee arthroplasty

Condition

- Joint disorders

Synonym
Osteoarthritis, Rheumatoid arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Arthroplasty, Knee, Knee prosthesis, Outcome, Replacement

Outcome measures

Primary outcome

For determining long term results of primary total knee arthroplasty, we use

the following encpoint:

Failure of the prosthesis, which is defined as:

- removal of the prosthesis

- recommended removal of the prosthesis (radiographic loosening)

- clinical failure

For determining the effect of preoperative parameters on clinical outcome, we

use regression analysis. Following outcome measures will be used:

- KSS score

- patient satisfaction

- quality of life

- daily functioning

- survival of the prosthesis

Secondary outcome

none

Study description

Background summary

Durability of total knee arthroplasty is an important issue for orthopaedic surgeons as well as patients. General belief is primary total knee arthoplasties last for ten to fifteen years. It is debatable if this information is correct. There is a paucity of follow-up studies with at least 15 years follow-up.
With respect to revision total knee arthroplasty, good or excellent clinical outcomes range from 40% to 89%. Patient expectations are strong predictors of outcome and functioning of joint replacement as well as satisfaction after joint replacement. Which clinical factors influence outcome of revision knee arthroplasty is insufficiently studied. These factors can help giving realistic prognosis of revision total knee arthroplasty and therefore improve clinical outcomes and patient satisfaction.

Study objective

Answer the following questions:

1. What are the long term results (>20y) of patients with a primary total knee prosthesis (type Total Condylar) for different endpoints:
a. Removal of the prosthesis. (with or without re-implantation)
b. Recommended removal: radiographic loosening
c. Clinical failure

2. Is survival of the prosthesis equal for rheumatoid arthritis in comparison with osteoarthritis?

3. Which preoperative clinical parameters determine clinical outcome (including patient satisfaction) of a revision total knee arthroplasty?

Study design

This protocol comprises an observational clinical cohort study. Data will be collected by investigation of medical files, clinical measurements and once filling in a number of questionnaires by patients. Questionnaires used are SF-36, EQ5D, OKS, KOOS, IPQ, and SQUASH. For determining clinical knee functioning we use Knee Society Score (KSS) or Hospital for Special Knee Score (HSS). Both scores have to be determined by a surgeon, in contrast to the other questionnaires. Information is collected until failure of the prosthesis or until patients have died.

For the study which analyses outcomes of revision TKA different models will be constructed for determining relationships between preoperative data (predictor variables) and several outcome variables.

Study burden and risks

Filling in the questionnaires will take approximately 30 minutes. Determining the HSS/KSS knee score will be performed at the department of Orthopedics in the LUMC and takes 10 minutes. Radiographic assessment will be done if this was not done within two years of the end of study. As much as possible will be tried to combine clinical and radiographic assessment with other appointments in the LUMC.

Subjects can leave the study at any time for any reason if they wish to do so without any consequences. Daily practice of follow-up of total knee arthroplasty is control at the department of Orthopaedics once every 2-3 years. Reason is early detection of wear of the prosthesis, before patients experience any discomfort.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
2333 ZA Leiden
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
2333 ZA Leiden
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patient underwent total knee arthroplasty (type Total Condylar) between 1-1-1979 and 31-12-1990 at AZL/LUMC. Or patient underwent revision total knee arthroplasty between 1-1-1993 and 31-12-2009 at AZL/LUMC.
Patient is capable of giving informed consent and expressing a willingness to comply with this study.
Patient is able and expressing willingness of filling in questionnaires regarding their operated knee(s) and daily function

Exclusion criteria

Patient is unable or unwilling to sign the Informed Consent specific to this study.
Patient is unable or unwilling of filling in the questionnaires regarding their operated knee(s) and daily funcion.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-01-2011
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO

Date:	04-01-2011

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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
Other	DTR: TC2218; UTN: U1111-1113-6472
CCMO	NL30498.058.09