Patients Prospectively Recruited in Knee and Hip Arthroplasty

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A. What are the determinants of quality of life of hip and knee replacement arthroplasty at long term follow-up?B. Which genetic factors are associated with aseptic loosening in hip and knee replacement arthroplasty? C. Which genetic determinants...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bone and joint therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON32983

Source
ToetsingOnline

Brief title
PaPRiKHA

Condition

- Bone and joint therapeutic procedures

Synonym
Hip / Knee Replacement Arthroplasty

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Aseptic loosening, Genetics, Illness perception, Quality of Life

Outcome measures

Primary outcome

Generic quality of life will be measured using the SF-36 and EQ-5D.

Illness-specific quality of life after hip replacement will be measured using the Oxford Hip Score (OHS) and the Hip disability and Osteoarthritis Outcome Score (HOOS).

Illness-specific quality of life after knee replacement will be measured using the Oxford Knee Score (OKS) en de Knee injury and Osteoarthritis Outcome Score (KOOS).

Secondary outcome

Aseptic loosening will be determined by specific questions on readmissions and revision surgery, and a thorough review of the clinical charts.

DNS polymorphisms will be selected in relevant candidate genes for the immune system or osteoarthritis. Genetic association analyses will be performed in a case-control design.

Study description

Background summary

A: Hip and knee replacement arthroplasties relieve pain and improve physical functioning and quality of life. However, some patients suffer from persisting

pain or are not satisfied with the outcome. Several studies have suggested risk factors for poor outcome after hip and knee replacement arthroplasty; however, most studied cohorts are relatively small (n<800), which makes correcting for confounding factors problematic. This larger cohort (n=3000) enables us to study all suggested risk factors and the possible correlations between them, while correcting for confounding factors.
By determining risk factors for poor outcome after hip and knee replacement arthroplasty, it will be possible to influence these factors, in order to optimalise the outcome of hip and knee replacement arthroplasty.

B: Aseptic loosening is the main cause of failure of hip and knee replacement arthroplasty in the long term. Several studies have suggested variances in immunomodulating genes as a possible contributor to aseptic loosening; however, group sizes were too small to draw any firm conclusions (n<90). In this current study, we aim to study the influence of immunomodulating genes on aseptic loosening in a larger patient cohort (n=3000) A better understanding of the underlying process of aseptic loosening will make it possible to determine the prognosis of prosthesis loosening more accurately.

C: Osteoarthritis is the most frequent indication for hip and knee arthroplasty. Conversely, the indication for hip and knee replacement arthroplasty can be viewed as the final stage in the pathophysiology of osteoarthritis. Recent studies showed that genetics play an important role in the pathophysiology of osteoarthritis. By comparing genetic variations between patients in final stage osteoarthritis and matched controls with a less severe clinical manifestation of osteoarthritis, a better understanding of the pathophysiology of osteoarthritis can be obtained.

Study objective

A. What are the determinants of quality of life of hip and knee replacement arthroplasty at long term follow-up?
B. Which genetic factors are associated with aseptic loosening in hip and knee replacement arthroplasty?
C. Which genetic determinants predispose to hip or knee replacement arthroplasty due to osteoarthritis?

Study design

Prospective cohort study:
- Measures for quality of life, hip and knee function and illness perception will be measured and repeated annually, until revision surgery is performed. The exact nature of the revision surgery will be examined in the clinical charts.

Case-control study:

- Gene frequencies will be compared between cases of aseptic loosening and controls.
- Genetic association studies will be performed, comparing patients who underwent hip or knee replacement with matched controls with a less severe manifestation of osteoarthritis.

Study burden and risks

Filling in the questionnaires will take approximately 20 minutes. These questionnaires will be sent to the patients, and will be returned by post-free envelope.

The genetic material will be isolated from a saliva sample. Patients will receive a special saliva container and will return the filled container by post-free envelope.

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

Participation in studies previously mentioned.

Exclusion criteria

None.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2010
Enrollment:	3000
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	09-12-2009
Application type:	First submission

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

ID: 24259
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL29018.058.09
OMON	NL-OMON24259