Patients Prospectively Recruited in Knee and Hip Arthroplasty.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24259

Source
NTR

Brief title
PAPRIKA

Health condition

Hip Replacement Arthroplasty
Knee Replacement Arthroplasty
Quality of Life
Aseptic loosening
Genetics
Illness perception

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: Dutch Arthritis Association

Intervention

Outcome measures

Primary outcome

Aseptic loosening.

Secondary outcome

Quality of life.

Study description

Background summary

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.

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.

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

1. What are the determinants of quality of life of hip and knee replacement arthroplasty at long term follow-up?

2. Which genetic factors are associated with aseptic loosening in hip and knee replacement arthroplasty?

3. Which genetic determinants predispose to hip or knee replacement arthroplasty due to osteoarthritis?

Study design

Patients will be sent questionnaires on Quality of Life every year, until revision hip or knee surgery takes place.

Questionnaires used are: Oxford Hip Score, Oxford Knee Score, HOOS, KOOS, Squash, EQ-5D, SF-36, IPQ en comorbiditeit according to CBS.

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

The study population consists of 3000 patients, who underwent hip or knee replacement, and were prospectively recruited in 2 previous studies (Trigger-study and TOMaat-study). We will extend the follow-up of these patients from 1-5 years postoperatively until revision hip or knee surgery takes place.

Exclusion criteria

None.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2009
Enrollment:	3000
Type:	Anticipated

Ethics review

Positive opinion

Date:	01-02-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 32983
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2073
NTR-old	NTR2190
CCMO	NL29018.058.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON32983

Study results

Summary results
N/A