Patients Prospectively Recruited in Knee and Hip Arthroplasty.

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24259

Bron
NTR

Verkorte titel
PAPRIKA

Aandoening

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

Ondersteuning

Primaire sponsor: Leiden University Medical Center
Overige ondersteuning: Dutch Arthritis Association

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Aseptic loosening.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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?

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

None.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-12-2009
Aantal proefpersonen:	3000
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	01-02-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 32983
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A