Predicting aseptic loosening of knee replacement prostheses through innate immunity.

No registrations found.

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

Summary

ID

NL-OMON29081

Source
NTR

Brief title
PRALINE

Health condition

Innate Immunity
Radio Stereometric Analysis
Aseptic Loosening
Knee Replacement Arthroplasty

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

1. Maximum Total Point Motion at 1 year, measured by RSA;

2. PAM3Cys and LPS-stimulated cytokine profiles.

Secondary outcome

N/A

Study description

Background summary

Aseptic loosening is the most common cause of failure of current joint replacement arthroplasties in the long term (>10 years after index surgery). Wear particles cause a sterile periprosthetic inflammatory process, which leads to osteolysis and formation of fibrous tissue. Pro-inflammatory cytokines play a major role in this process.

Micromotion preceeds aseptic loosening and can be accurately measured by RSA. RSA measurements can only be performed if tantalum markers are inserted during surgery.

Innate immunity can be determined at any time, even pre-operatively. Innate immunity may even be a useful tool in predicting the preoperative risk of aseptic loosening.

Study objective

What does the non-specific cytokine response contribute to the prediction of prosthesis fixation (expressed in MTPM after 1 year), compared with simple patient characteristics?

Study design

Patients will undergo a single venipuncture, to obtain 32ml of blood.

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients over 18 years, who underwent elective knee replacement arthroplasty;

2. Patients who are part of an RSA-cohort and whose MTPM at 1 year have been measured.

Exclusion criteria

1. No measurable MTPM at 1 year, or inadequate registration;

2. Tibia component in frontal plane greater than 5 ° varus or valgus 5.

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:	Pending
Start date (anticipated):	01-03-2010
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

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

Study registrations

Followed up by the following (possibly more current) registration

ID: 32587
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2081
NTR-old	NTR2197
CCMO	NL30892.058.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON32587

Study results

Summary results
N/A