PRedicting Aseptic Loosening through InnatE immunity

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

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON32587

Source
ToetsingOnline

Brief title
PRALINE

Condition

- Other condition
- Joint disorders
- Bone and joint therapeutic procedures

Synonym
knee prosthesis, knee replacement arthroplasty

Health condition

knieprothese

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Aseptic Loosening, Innate Immunity, Knee Replacement Arthroplasty, Radio Stereometric Analysis

Outcome measures

Primary outcome

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

PAM3Cys and LPS-stimulated cytokine profiles.

Secondary outcome

NA.

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 years), compared with simple patient characteristics?

Study design

Observational study.

Study burden and risks

The burden for the patient consists of a single venipuncture, to obtain 4 tubes of blood (32ml).
The foremost risk is a hematoma, there is also a small chance of a phlebitis.

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

- Patients over 18 years, who underwent elective knee replacement arthroplasty.
- Patients who are part of an RSA-cohort and whose MTPM at 1 year have been measured.

Exclusion criteria

- No measurable MTPM at 1 year, or inadequate registration.
- Tibia component in frontal plane greater than 5 ° varus or valgus 5.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2010
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	28-01-2010
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

ID: 29081
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL30892.058.09
OMON	NL-OMON29081