Systemic Metal Ion Concentrations in Patients with a PEEK HD coupling mechanism in the Modular Mega-prostheses of the Knee; a prospective cohort pilot study

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Objective: We aim to 1) monitor and investigate the change in serum metal ion (Cobalt and Chrome) levels postoperatively (at 3-6, 12 and 24 months) in patients receiving a primary PEEK HD coupling mechanism, monitor and investigate the change in…

Ethical review	Approved WMO
Status	Pending
Health condition type	Joint disorders
Study type	Observational invasive

Summary

ID

NL-OMON56747

Source
ToetsingOnline

Brief title
Metal-ions in patients with the PEEK HD coupling mechanism of the knee

Condition

- Joint disorders
- Soft tissue neoplasms malignant and unspecified
- Bone and joint therapeutic procedures

Synonym
Serum level of metal ions

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,ImplantCast GmbH

Intervention

Keyword: megaprostheses, metal-ions, MUTARS, PEEK-HD

Outcome measures

Primary outcome

Serum metal ion concentrations Cobalt (Co) and Chrome (Cr) pre- and postoperatively (at 3-6, 12 and 24 months)

Secondary outcome

Secondary parameters are used to identify any adverse effects in patients with increased serum levels of ion metals (metallosis, osteolysis, periprosthetic loosening, pseudotumor formation).

Tertiary parameters are used to identify possible risk factors correlating with metal-ion release.

Quaternary parameters (PROMIS 29 or TESS) are used to evaluate the functional outcome of the patient. All other variables (e.g. general baseline characteristics, treatment characteristics, and surgical details including prosthesis details) will be gathered to describe the study population.

Study description

Background summary

Local release of metal ions and their systemic sequelae is an increasing source of concern in patients with an endoprosthetic reconstruction of major joints. It is assumed that metal-on-metal (MoM) articulations, used in several types of mega-prostheses, may cause release of metal ions. Corrosion of non-articulating surfaces, abrasive wear of soft tissues and fretting of modular junctions could contribute to this release. The release of metal ions are known to induce inflammatory responses and immune reactions in the directly exposed tissues and can cause serious local adverse reactions such as metallosis, osteolysis, pseudotumor formation and systemic adverse effects such as cardiovascular and neurological adverse effects. Our study group previously found significantly elevated serum levels of Silver (Ag), Chrome (Cr) and Cobalt (Co) in a series (not published yet) of 11 patients with a MoM coupling mechanism of knee endoprostheses. Furthermore, we have recently encountered a number of early mechanical failures of these MoM coupling mechanisms. The implant manufacturer (ImplantCast GmbH) recently introduced a carbon-reinforced PEEK HD (polyether ether ketone high demand) coupling mechanism in an attempt to reduce the risk of early mechanical failure and to lower the risk on the release of metal ions. Based on the outcomes of previous research and the mechanical failures of the MoM coupling mechanism, we will switch to the use of the new (approved and CE-marked) PEEK HD coupling mechanism. We hypothesize that the PEEK HD coupling mechanism will not result in elevated serum metal ion levels in patients receiving a mega prosthesis.

Study objective

Objective: We aim to 1) monitor and investigate the change in serum metal ion (Cobalt and Chrome) levels postoperatively (at 3-6, 12 and 24 months) in patients receiving a primary PEEK HD coupling mechanism, monitor and investigate the change in serum metal ion levels pre-and postoperatively (at 0, 3-6, 12 and 24 months) in patients with an MoM coupling mechanism which is revised to a PEEK HD coupling mechanism (in case of failure for any reason), 2) document adverse effects caused by metal ions, 3) report factors (possibly) correlating with metal ion release and 4) evaluate the functional outcome of the patient using the Patient-Reported Outcome Measurement Information System (PROMIS) 29 and or Toronto Extremity Salvage Score (TESS) lower extremity.

Study design

This is a prospective cohort pilot study to evaluate metal ion concentrations, possible adverse effects and functional outcomes after the implantation of a PEEK HD coupling mechanism.

Study burden and risks

Serum metal ion concentrations (Cobalt and Chrome) will be determined at 0, 3-6, 12, and 24 months postoperatively. The potential benefits of routine determination of metal ion concentrations are early detection of toxic values of metal ions. Except for the negligible risks of routine venepuncture no potential risks are anticipated.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria: The patient

1) is 18 years of age or older
2) receives a MUTARS knee replacement with PEEK HD coupling mechanism, or undergoes a revision (for any reason) of a MUTARS knee replacement during which the MoM coupling mechanism is revised for a PEEK HD coupling mechanism
3) Is able to give informed consent

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
1) Anamnestic use of metal containing nutritional supplements or medications
2) Contact with metal ions in the work environment
3) Renal insufficiency defined as an eGFR<60 ml/min
4) Presence of implants containing Cobalt and Chrome (including non-orthopaedic implants such as stents and dental implants)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2024
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Generic name:	MUTARS knee endoprosthesis
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	14-05-2024
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

No registrations found.

In other registers

Register	ID
Other	NL82185.058.22
CCMO	NL82185.058.24