Systemic Metal Ion Concentrations in Patients with Modular Megaprostheses

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(1) We aim to quantify systemic metal ion concentrations ions (Ag/Co/Cr/Mo/Ti/Al/V) before and after megaprosthesis arthroplasty in blood serum, (2) identify factors correlated to ion release in megaprostheses, (3) document adverse effects caused by…

Ethical review	Approved WMO
Status	Pending
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Observational invasive

Summary

ID

NL-OMON45380

Source
ToetsingOnline

Brief title
Metal Ions

Condition

- Bone disorders (excl congenital and fractures)

Synonym
bonetumors, Sarcoma

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Ions, Limb Salvage, Megaprostheses, Metal

Outcome measures

Primary outcome

(1) Serum metal ion concentrations of Silver (Ag), Cobalt (Co), Chrome (Cr),

Molybdenum (Mo), Titanium (Ti), Aluminium (Al), Vanadium (V) during follow up.

Secondary outcome

(1) Adverse effects (metallosis, osteolysis, periprosthetic loosening,

pseudotumour formation and argyria) (2) Quality of life and functional status

using SF-36 and TESS.

Study description

Background summary

Systemic and local release of metal ions in endoprosthesis arthroplasty is an increasing source of concern. It is assumed that release of metal ions is caused by metal-on-metal articulations used in several types of megaprostheses. However, corrosion of non-articulating surfaces, abrasive wear of soft tissues and fretting of modular junctions could contribute to release of metal ions. In addition; silver coatings have been developed to purposefully release silver metal ions in the case of an infection.
Release of metal ions is known to induce inflammatory responses and immune reactions in the directly exposed tissues. In literature serious local adverse reactions such as metallosis, osteolysis, and pseudotumor formation are reported.
Systemic exposure to metal ions in blood serum has been demonstrated in metal-on-metal prostheses as well as in megaprostheses. What adverse effects emerge, as a result of systemic metal ion dissemination, is not fully known. In the case of cobaltism, mainly cardiovascular and neurological adverse effects are reported. Silver ions are reported to cause argyria, neuropathy, hepatic and renal failure. Little solid data is published concerning adverse effects, especially in the case of high metal ion concentrations of Chrome, Molybdenum, Titanium, Aluminium and Vanadium.
Since mid and long-term prospective data on metal ion dissemination in

megaprostheses is lacking, we will perform a prospective study to investigate metal ion concentrations before and after megaprostheses implantation. Because a large proportion of adverse effects associated with high systemic metal ion concentrations overlap with adverse effects associated with chemotherapy emphasis will be laid on local adverse effects.

Study objective

(1) We aim to quantify systemic metal ion concentrations ions (Ag/Co/Cr/Mo/Ti/Al/V) before and after megaprosthesis arthroplasty in blood serum, (2) identify factors correlated to ion release in megaprostheses, (3) document adverse effects caused by metal ions.

Study design

This study is a prospective cohort study to evaluate metal ion concentrations, factors correlated to metal ion release and adverse effects after megaprosthesis implantation.

Study burden and risks

All patients participating in this study will be asked to visit the outpatient clinic at 12 weeks, 12 months, and then annually up to 5 years postoperatively to determine serum metal ion concentrations (Ag/Co/Cr/Mo/Ti/Al/V). X-ray imaging will be performed. Patients will be asked to fill out quality of life and functional status questionnaires (SF-36 and TESS). Magnetic resonance imaging (MARS sequence) will be performed at the annual follow up points. Outpatient visits, questionnaires, blood sampling, x-ray and magnetic resonance examinations can be seen as a part of routine patient care. Potential benefits of routine determination of metal ion concentrations could be early detection of toxic values of metal ions. Except for the negligible risks of routine venepuncture no potential risks are anticipated.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-Males and females, 18 years of age or older
-Primary treatment by endoprosthetic reconstruction with a MUTARS modular megaprosthesis (all types of MUTARS, including expandable prostheses, are acceptable)
-Provision of informed consent

Exclusion criteria

-Revision surgery of any type of metallic prosthesis
-Anamnestic use of metal containing nutritional supplements or medications
-Contact with metal ions in the work environment
-Renal insufficiency defined as an eGFR<60
-Patient refusal to participate in the study
-Likely problems, in the judgement of the investigator, with maintaining follow-up

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):	17-03-2017
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Generic name:	Venipuncture
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	10-07-2017
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
CCMO	NL61035.058.17