Ototoxicity in patients with Metal-on-Metal hip Arthroplasties

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To evaluate the prevalence of ocular-vestibular symptoms in patients with a (revised) MoM hip prosthesis. Our hypothesis is that patients with high plasma metal ion levels have a higher prevalence of damage to the auditory system.

Ethical review	Approved WMO
Status	Completed
Health condition type	Hearing disorders
Study type	Observational invasive

Summary

ID

NL-OMON56425

Source
ToetsingOnline

Brief title
Ototoxicity with Metal-on-Metal hip bearings

Condition

- Hearing disorders
- Bone and joint therapeutic procedures

Synonym
hearing loss, ototoxicity

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep
Source(s) of monetary or material Support: Reinier de Graaf Ziekenhuis

Intervention

Keyword: Arthroplasty, Cobalt, Metal-on-metal, Ototoxicity

Outcome measures

Primary outcome

To assess the prevalence of damage to the auditory system in patients with a Metal-on-Metal or revised Metal-on-Metal bearing, especially regarding mid frequency hearing loss. A distinction will be made between prevalence in patients with high plasma cobalt or chromium levels and patients with low plasma cobalt and chromium levels.

Secondary outcome

To assess which factors are associated with damage to the auditory system (We will only perform this if possible, if we have enough cases with hearing loss).

o Factors of interest: highest known cobalt plasma concentration, highest known chromium plasma concentration, type of prosthesis, age, work in a noisy environment, presence of ARDM, revision

o Patients will be asked to complete the hearing questionnaire as well as the Metal-on-Metal Prosthesis Questionnaire for Assessing General Health in order determine the general health of these patients and subjective hearing loss.

Study description

Background summary

Patients with a Metal-on-Metal (MoM) hip prosthesis have an increased risk of elevated serum metal ions. High plasma levels of cobalt (Co) and chromium (Cr) are associated with local and systemic adverse reactions. Ototoxicity, such as hearing loss, tinnitus and dizziness, could be related to high plasma levels of

these ions.

Study objective

To evaluate the prevalence of ocular-vestibular symptoms in patients with a (revised) MoM hip prosthesis. Our hypothesis is that patients with high plasma metal ion levels have a higher prevalence of damage to the auditory system.

Study design

Multi-centre cohort study.

Study burden and risks

The burden is primarily time, one/two (online/home) questionnaire(s) and one visit to the outpatient ENT department. During that visit we will also obtain a blood sample.*

Contacts

Public
Reinier de Graaf Groep

Reinier de Graafweg 5
Delft 2625 AD
NL
Scientific
Reinier de Graaf Groep

Reinier de Graafweg 5
Delft 2625 AD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

All MoM patients from the different clinics
Revision MoM
Willing to participate
Speak/write the Dutch language.

Exclusion criteria

Not willing to participate
Previous ENT surgery or ENT pathology

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	24-03-2023
Enrollment:	450
Type:	Actual

Ethics review

Approved WMO Date:	05-08-2022
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	10-03-2023
Application type:	Amendment
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	NL79241.058.22