Magnesium variability study in haemodialysis patients: intra-patient and inter-patient variability of plasma magnesium before and after hemodialysis.

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To assess intra- and interpatient variability of plasma Mg concentration before and after hemodialysis.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational non invasive

Summary

ID

NL-OMON42883

Source
ToetsingOnline

Brief title
Magnesium variability study

Condition

- Cardiac disorders, signs and symptoms NEC
- Nephropathies
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
endstage renal disease, kidney disease

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Nierstichting

Intervention

Keyword: hemodialysis, magnesium, variability

Outcome measures

Primary outcome

Main parameters: Plasma Mg before and after dialysis in 6 consecutive hemodialysis sessions, determined in duplicate.

Main endpoints: The intra-individual pre-dialysis variability and post-dialysis (dialysis-induced) variability of plasma Mg and the interindividual variability of pre-dialysis and post-dialysis plasma Mg.

Secondary outcome

- The difference in point-estimate of plasma Mg concentration before and after dialysis, using a fixed standard dialysate Mg concentration, as a function of predialysis Mg concentration.
- Factors that predict larger differences in point-estimates of plasma Mg before and after dialysis.

Study description

Background summary

Cardiovascular disease is the leading cause of death in patients with chronic kidney disease (CKD). Traditional risk factors account for only part of this risk. Identification of new risk factors, might facilitate therapy changes to improve prognosis in patients with CKD. Magnesium (Mg) has recently gained attention. In observational studies in hemodialysis patients, lower Mg levels

were associated with overall and cardiovascular mortality. In vitro studies showed inhibition of calcification of vascular smooth muscle cells in the presence of Mg. Based on these data, we hypothesize that Mg is a new modifiable risk factor for cardiovascular disease in CKD. Before proceeding to intervention trials with clinically relevant endpoints, targeting relatively low plasma magnesium levels in hemodialysis patients, information on variability of plasma Mg levels in these patients is needed. Currently however no reliable observational data are available in the literature describing the within-subject biological variability of Mg concentrations in haemodialysis patients before and after dialysis with a fixed concentration of Mg in the dialysate. Information on variability is critical, to ensure safety for individual patients when increasing plasma Mg levels, but also to enable formal power-calculations to estimate the numbers of subjects required for future interventional studies.

Study objective

To assess intra- and interpatient variability of plasma Mg concentration before and after hemodialysis.

Study design

Observational single-center study.

Study burden and risks

Patient effort is minimal for this study. Blood samples (3mL each) will be taken before and after dialysis in six consecutive hemodialysis sessions, during a period of two weeks. The blood samples can be taken from the dialysis circuit so no additional puncture is needed. No additional risks are involved. There are no direct advantages for patients participating in this study. The study might facilitate the adequate design of future trials targeting relatively low plasma Mg.

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

- Age *18
- Hemodialysis with regular three times weekly dialysis schedule
- Hemodialysis since at least 3 months
- Standard dialysate Mg2+ 0.5 mmol/L
- Providing informed consent

Exclusion criteria

- Age <18
- Intravenous magnesium supplementation that has been started or stopped in the last 2 weeks, or the subject currently receives non-continuous magnesium supplementation. Note: subjects receiving stable continuous intravenous magnesium supplementation including total parenteral nutrition since at least 2 weeks can be included.
- Expected cessation of dialysis treatment within 2 weeks after inclusion.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-09-2016
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	15-07-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL57914.029.16