MAGnesium In Chronic HemoDialysis; A clinical trial assessing the feasibility of increasing plasma magnesium concentrations by means of increasing dialysate magnesium concentrations in chronic hemodialysis patients.

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Main Objective: - Determine feasibility to increase plasma magnesium concentrations in hemodialysis patients by means of increased concentration of magnesium in the dialysate. Secondary Objectives:- Determine safety of increasing plasma magnesium...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON48731

Source
ToetsingOnline

Brief title
MAGIC-HD

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: Chronic kidney disease, Hemodialysis, Magnesium

Outcome measures

Primary outcome

- The difference between plasma magnesium concentration in the intervention group and plasma magnesium concentration in the control group after the long interdialytic interval at the end of week 8.

- The difference in change of plasma magnesium concentration after the long interdialytic interval from baseline to the end of week 8 between the intervention and the control group.

Secondary outcome

- The cumulative incidence of magnesium concentration >= 1.25 mmol/L in the intervention group and in the control group.

- The cumulative incidence of prolonged duration of QTc (defined as >450ms in male and >460ms in female) in the intervention group and in the control group.

- The cumulative incidence of bradycardia (defined as heart rate below 60 beats per minute) in the intervention group and in the control group.

- The effect of dialysate magnesium concentration on pre-dialysis and post-dialysis plasma magnesium concentration at the dialysis after the long interdialytic interval.

- Predictive factors for the effect of dialysate magnesium concentration on pre-dialysis and post-dialysis plasma magnesium concentration at the dialysis after the long interdialytic interval.

- The difference in carotid-femoral pulse wave velocity in the intervention group and the control group in week 8, and the difference in change of pulse wave velocity from baseline to week 8 between the intervention group and the control group.

Study description

Background summary

In hemodialysis patients, the risk for mortality and especially cardiovascular mortality is substantially higher compared to the healthy population. This risk can only partially be explained by traditional cardiovascular risk factors and known kidney specific risk factors. In observational hemodialysis cohort studies, lower serum magnesium levels are associated with overall and cardiovascular mortality. It is currently unknown whether increasing plasma magnesium concentrations in hemodialysis patients can decrease cardiovascular mortality. To enable future studies on this topic, we first need to optimize methods to increase plasma magnesium concentrations. In hemodialysis patients, the dialysate might be an attrative route. Literature on the effect of increasing dialysate magnesium concentrations on pre- and postdialysis plasma magnesium is insufficient. This study can provide important information to enable future studies focussed on improving cardiovascular outcome in hemodialysis patients.

Study objective

Main Objective:
- Determine feasibility to increase plasma magnesium concentrations in hemodialysis patients by means of increased concentration of magnesium in the dialysate.
Secondary Objectives:
- Determine safety of increasing plasma magnesium concentrations by means of increasing the concentration of magnesium in the dialysate.
- Determine the effect of dialysate magnesium concentrations on plasma magnesium concentrations.

- Determine which parameters are predictive for the effect of dialysate magnesium concentrations on plasma magnesium concentrations.

Study design

Randomized double-blind standard of care-controlled intervention trial.

Intervention

Stepwise increase of magnesium concentration in the dialysate:
- Week 0: continuation of standard 0.50 mmol/L dialysate magnesium
- Week 1, 2, 3, 4: dialysate magnesium 0.75 mmol/L
- Week 5, 6, 7, 8: dialysate magnesium 1.00 mmol/L if pre-dialysis plasma Mg <1.15 mmol/L in week 4; dialysate magnesium 0.75 mmol/L if pre-dialysis plasma Mg >=1.15 in week 4
- Week 9: dialysate magnesium concentration reduction of 0.25 mmol/L (to either 0.75 mmol/L or 0.50 mmol/L)
- Week 10, 11: dialysate magnesium 0.50 mmol/L

Study burden and risks

Burden and risks associated with participation:
- Blood sampling: before and after dialysis weekly from week 0 to 11 and every dialysis session in week 1 and 5. Samples are taken from the dialysis circuit so no additional puncture is needed.
- Questionnaires: 3 times 10 minutes
- 3-days dietary record: once
- ECG 3 times at the dialysis department
- Pulse wave velocity measurements 2 times at the dialysis department
- Holter-registrations: 2 times, installation of electrodes, 48h with the device, no showering/swimming/sauna
- There is a very small risk for symptomatic hypermagnesemia. Symptoms of severe hypermagnesemia typically do not develop at concentrations below 2.0 mmol/L and include nausea, vomiting, prolonged cardiac conduction times (QTc), bradycardia, hypotension, muscle weakness and decrease of conscience. The dialysate magnesium levels used in this study are not expected to cause magnesium levels in this range and this risk is further minimized by intensive monitoring of plasma magnesium levels and electrocardiography.

Benefits:
- There are no benefits for individual patients participating in this study. However, this study can provide important information to enable future studies focusing on improving cardiovascular outcome in hemodialysis patients.

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 or above
- Hemodialysis with regular three times weekly dialysis schedule
- Hemodialysis since at least 3 months
- Standard dialysate Mg2+ concentration 0.50 mmol/L
- Providing informed consent
- Pre-dialysis plasma magnesium concentration 1.00 mmol/L or below

Exclusion criteria

- Intravenous magnesium supplementation (including total parenteral nutrition) in the last 2 weeks

- Expected cessation of hemodialysis treatment within three months after inclusion or expected permanent or temporary dialysis center switch to a center not participating in the trial within three months after inclusion.
- Prolongation of QTc interval: male >450ms or female >460ms on baseline ECG
- Bradycardia: heart rate below 60 beats per minute on baseline ECG
- Chronic arrythmia or cardiac conduction disorder other than atrial fibrillation or ventricular extrasystole that poses the patient at risk at the discretion of the treating physician.
- Change of protonpumpinhibitor prescription in the last 2 weeks

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-02-2018
Enrollment:	53
Type:	Actual

Ethics review

Approved WMO Date:	18-10-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-01-2018

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-12-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-09-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-07-2020
Application type:	Amendment
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

ID: 23476
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL62679.029.17
Other	registratie in behandeling, nummer volgt
OMON	NL-OMON23476