MAGnesium in Chronic HemoDialysis

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23476

Source
NTR

Brief title
MAGIC-HD

Health condition

chronic kidney disease, end-stage renal disease

chronische nierziekte, eindstadium nierfalen

Sponsors and support

Primary sponsor: VU University Medical Center
Source(s) of monetary or material Support: Dutch Kidney Foundation, project ID 15Op02

Intervention

Outcome measures

Primary outcome

- The difference between plasma magnesium concentration after the long interdialytic interval in the intervention group with incremental dialysate magnesium concentration and plasma magnesium concentration in the control group with standard dialysate magnesium

concentration 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 group and the control group.

Secondary outcome

- The cumulative incidence of magnesium concentration 1.25 mmol/L or above 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.

Linked to this clinical trial, a bio bank is set up. Blood for biobanking is collected from participants who provide additional informed consent for biobanking. An outcome parameter from this material is:
- The difference in calcification propensity score (T50) in the intervention group and the control group in week 8, and the difference in change of calcification propensity score from baseline to week 8 between the intervention group and the control group.

Study description

Background summary

Background: In observational hemodialysis cohort studies, lower serum magnesium levels are associated with overall and cardiovascular mortality. In vitro, magnesium inhibits calcification of vascular smooth muscle cells. Based on these data, we hypothesize that lower magnesium

is a new risk factor for cardiovascular disease in CKD. The dialysate might be an attractive way to increase plasma dialysate concentration.

Objective/Research questions: Determine feasibility to increase plasma dialysate magnesium concentration by means of increasing dialysate magnesium concentration.

Methods: A prospective randomized double blind standard of care controlled trial in patients on a regular 3 times weekly hemodialysis schedule. The control group continues dialysis with the standard dialysate magnesium concentration of 0.50 mmol/L. In the intervention group, the dialysate magnesium concentration is step-wise increased from 0.50 mmol/L to 0.75 mmol/L to 1.00 mmol/L, followed by a gradual decrease to the standard dialysate magnesium concentration of 0.50 mmol/L.

Primary outcome:

1. The difference between plasma magnesium concentration after the long interdialytic interval in the intervention group with incremental dialysate magnesium concentration and plasma magnesium concentration in the control group with standard dialysate magnesium concentration at the end of week 8.

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

Country of recruitment: The Netherlands

Study objective

Increasing plasma magnesium concentration in hemodialysis patients by means of increasing dialysate magnesium concentration is feasible.

Study design

- week 0-11 plasma magnesium measurements

- week 0, 4, 8 study visit

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 or above 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

Contacts

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Eligibility criteria

Inclusion criteria

- Age 18 years or above

- Hemodialysis with regular three times weekly dialysis schedule

- Hemodialysis since at least 3 months

- Standard dialysate Mg2+ 0.50 mmol/L

- Providing informed consent

- Pre-dialysis plasma magnesium concentration not higher than 1.00 mmol/L

Exclusion criteria

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

- Expected cessation of dialysis 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

Recruitment

NL

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

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion
Date: 14-07-2017
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48731
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6393
NTR-old	NTR6568
CCMO	NL62679.029.17
OMON	NL-OMON48731

Study results