MAGnesium in Chronic HemoDialysis

Gepubliceerd: 14-07-2017 Laatst bijgewerkt: 19-03-2025

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23476

Bron
NTR

Verkorte titel
MAGIC-HD

Aandoening

chronic kidney disease, end-stage renal disease

chronische nierziekte, eindstadium nierfalen

Ondersteuning

Primaire sponsor: VU University Medical Center
Overige ondersteuning: Dutch Kidney Foundation, project ID 15Op02

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- 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.

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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

Onderzoeksopzet

- week 0-11 plasma magnesium measurements

- week 0, 4, 8 study visit

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	08-02-2018
Aantal proefpersonen:	53
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	14-07-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48731
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten