Effect of calcium and citrate dialysate concentrations on the calcification propensity in hemodialysis; a prospective randomized controlled cross-over trial.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone, calcium, magnesium and phosphorus metabolism disorders
Study type	Interventional

Summary

ID

NL-OMON44984

Source
ToetsingOnline

Brief title
The calcification propensity of uremic patients on hemodialysis.

Condition

- Bone, calcium, magnesium and phosphorus metabolism disorders
- Renal disorders (excl nephropathies)
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Calcification propensity of serum of hemodialysis patients. Vascular calcification.

Research involving
Human

Sponsors and support

Primary sponsor: Interne Geneeskunde, Nefrologie
Source(s) of monetary or material Support: Fresenius Medical Care,unrestricted grant Fresenius Medical Care Bad Homburg Germany

Intervention

Keyword: Calcification propensity, Calcium dialysate concentrations, Citrate dialysis, Hemodialysis

Outcome measures

Primary outcome

* Calcification propensity assessed by the transition time T50 from primary to

secondary CPP by time-resolved nephelometry (T50).

Secondary outcome

* Pulse wave velocity (PWV) measured with a SphygmoCor pulse wave velocity

meter.

* Heart rate variability (HRV) measured with a Taskforce monitor.

* Total mass balances of calcium and phosphate by direct dialysis

quantification.

Study description

Background summary

In chronic hemodialysis (HD) patients managed with thrice weekly HD, the mortality due to cardiovascular events remains high despite of all the technological improvements of this therapy in the last years. It has been shown that an increased vascular calcification is directly correlated to an increased cardiovascular mortality. In dialysis patients abnormalities in mass transport of calcium and phosphate, which are involved in formation of calciprotein particles (CPPs) could play a pathogenic role. The calcification propensity of serum, measured by a novel T50 test, measures the transformation time from primary to secondary CPPs and is highly predictive of all-cause mortality in HD

patients. In a recent study it was shown that phosphate removal during dialysis strongly improved the T50. However, less is known on the influences of dialysate calcium on the formation of CPP or on the role of calcium-citrate dialysate, in which citrate is a calcium chelator.

Study objective

The first objective of this study is to evaluate the effect of standard HD with different dialysate calcium concentrations as well as HD combined with citrate-acid dialysate on the clearance of CPPs and second the effect of these different solutions on cardiovascular parameters.

Study design

Twenty-two prevalent conventional high-flux HD (CHD) patients will undergo, in a random prospective design, 1 week standard high-flux HD with DCa1.50 (treatment A) followed by either citrate acid-dialysate HD (treatment B) or high-flux HD with DCa1.25 (treatment C) for 1 week, followed by a wash-out period of 1 week on standard high-flux HD with DCa1.50 (treatment A), followed by either citrate acid-dialysate HD (treatment B) or high-flux HD with DCa1.25 (treatment C) for 1 week.

Intervention

In the study 22 HD patients will be treated in a randomized order with either a dialysate calcium (DCa) of 1.25 mmol/l (DCa 1.25), a DCa of 1.50 mmol/l (DCa 1.50), or citrate-acid dialysate (containing 1.5 mmol/l calcium) for 3 treatments (1 week) each.

Study burden and risks

In this study, only non-invasive techniques which pose a minimal burden to the patient will be used. Blood sampling, HRV-, and the PWV-measurements will be combined with regular blood takings when patients are present in their dialysis unit. The different dialysate calcium concentrations as well as citric-acid dialysate are registered products and used in routine practice.

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

Prevalent HD patients with a dialysis vintage of at least 3 months.
Hemodynamically stable on dialysis.
AV-fistula enabling double-needle vascular access or tunneled central venous dialysis catheter with a blood flow rate of at least 300 ml/min.
Age above 18 years of age.
Informed consent.

Exclusion criteria

Withdrawal of consent
Acute intercurrent illness (infection, malignancy, cardiovascular event, uncontrolled diabetes)
Long QT syndrome
Frequent intra-dialytic hypotension (>10% of treatments)

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-04-2017
Enrollment:	22
Type:	Actual

Ethics review

Approved WMO

Date:	07-12-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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: 28230
Source: NTR
Title:

In other registers

Register	ID
Other	NTR5226
CCMO	NL53094.068.15
OMON	NL-OMON28230

Study results

Date completed:	12-10-2017
Actual enrolment:	20