Potassium handling in chronic hemodialysis patients in response to higher dialysate potassium

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To analyze how potassium handling, volume and sodium status change in stable anuric chronic hemodialysis patients (CKD-5D) in response to higher dialysate potassium.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Nephropathies
Study type	Interventional

Summary

ID

NL-OMON55533

Source
ToetsingOnline

Brief title
K+ Balance in Hemodialysis

Condition

- Nephropathies

Synonym
CKD-5D, End-Stage-Renal-Disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: CKD-5D, Dialysate potassium, Serum potassium, Total body K+ (TBK)

Outcome measures

Primary outcome

The primary outcome will be RBC potassium (mmol/L)

Secondary outcome

Secondary endpoints will include serum potassium, potassium removal, serum sodium, sodium removal, total ultrafiltration volume, total body water, and systolic blood pressure as well as changes in serum bicarbonate, insulin, and plasma aldosterone.

Study description

Background summary

In hemodialysis patients hyperkalemia is often attributed to dietary potassium intake. Currently, hemodialysis patients are advised to adhere to a potassium restricted diet. Some differentiations, however, are to be made. That is, hyperkalemia may also be caused by changes in the internal potassium balance. A cohort study showed that urea levels, metabolic acidosis, and hyperglycemia but not anuria or hyperkalemic drugs were associated with pre-dialysis serum potassium concentrations.[1] Moreover, as in non-dialysis CKD, TBK has been shown to be decreased in dialysis patients. Importantly, one study by Adrogué*s group indicated that lower TBK in hemodialysis patients has prognostic impact. The median survival was 55 months in TBK-depleted subjects vs. 100 months in subjects with normal TBK. The same group showed that lowering of serum potassium by the dialysate resulted in higher blood pressure one hour post-dialysis. Moreover, serial measurements of total body minerals showed that a TBK increment was associated with lower total body sodium, although other studies could not reproduce this observation. In summary, a higher potassium dialysate concentration (4 mmol/l) may restore TBK. Whether this would also lead to improved blood pressure regulation, sodium removal, and volume control is unknown.

Study objective

To analyze how potassium handling, volume and sodium status change in stable anuric chronic hemodialysis patients (CKD-5D) in response to higher dialysate potassium.

Study design

Single-blind, interventional cross-over study

Intervention

Hemodialysis patients will be treated for 4 weeks using widely used dialysate solutions as part of standard care containing potassium either 2 mmol/L or 4 mmol/L in random order.

Study burden and risks

Participating in this research project will not lead to personal benefit. However, higher dialysate potassium might lead to better (intradialytic) blood pressure and volume control. Because of study-related non-invasive and invasive measurements, including skin biopsies, additional burden is expected when participating in this study. The subjects undergo hemodialysis 3 x 4 hrs/week. There will be one screening visit and two study visits, which will take place during regular hemodialysis treatment. The study visits, including hemodialysis, will take 2 hours extra in total. Study procedures include: venous blood drawings, skin biopsies, measurements of volume status (using weight and bioimpedance measurements), ECG recordings and central and peripheral hemodynamics (by using continuous finger arterial pressure [FinAp] waveform registration, Nexfin®. Futhermore, we will analyse the microcirculation under the tongue using a sidestream dark field (SDF) camera. A higher dialysate potassium concentration may incur development of hyperkalemia. For that reason, pre-dialysis serum potassium will be measured weekly. In case serum potassium exceeds >=6 mmol/L or becomes lower thand 3.0 mmol/L patients will leave the study.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam-Zuidoost 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam-Zuidoost 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Adult (age >= 18 years) stable anuric hemodialysis patients that undergo treatment 3 x 4 hrs/week.
• Written informed consent

Exclusion criteria

• Pre-dialysis serum potassium <4.0 mmol/L or > 6.0 mmol/L or use of potassium binders
• Patients with previous history of ventricular cardiac arrhythmia.
• Uncontrolled hypertension (systolic BP >180 mmHg on at least 3 of the last 5 dialysis treatments) or intradialytic hypotension on >3 dialysis treatments in the last month
• Patients with insulin dependent diabetes mellitus
• Patients with a life expectancy < 6 months.
• Expected kidney transplantation < 2 months.
• Cognitively impaired or incapacitated subjects.
• Women who are pregnant, breastfeeding or consider pregnancy in the coming 6 months.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-12-2019
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Dialysate
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	13-11-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-01-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-09-2021
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

No registrations found.

In other registers

Register	ID
CCMO	NL66478.018.18