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

No registrations found.

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

Summary

ID

NL-OMON23110

Source
NTR

Brief title
K+ Balance in Hemodialysis

Health condition

Chronic Kidney Disease, End-Stage Renal Disease

Sponsors and support

Primary sponsor: AUMC - AMC
Source(s) of monetary or material Support: Dutch Kidney Foundation

Intervention

Outcome measures

Primary outcome

The primary outcome will be RBC potassium.

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

Rationale:
In hemodialysis patients, hyperkalemia is often attributed to dietary potassium intake. 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. Moreover, as in non-dialysis CKD, total body potassium (TBK) has been shown to be decreased in dialysis patients. Importantly, a lower TBK in hemodialysis patients provides prognostic information as median survival was recorded to be 55 months in TBK-depleted subjects vs. 100 months in subjects with normal TBK. Lowering of serum potassium by the dialysate was associated with higher blood pressure levels one hour post-dialysis. Moreover, serial measurements of total body minerals showed that a TBK increment was associated with lower total body sodium (TBNa), although other studies could not reproduce this observation.[1],[2] In summary, a higher potassium dialysate concentration may restore TBK. Whether this would also lead to improved blood pressure regulation, increased sodium removal, and better volume control is unknown.

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.

Study population: Stable anuric hemodialysis patients that undergo treatment 3 x 4 hrs/week.

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

Main study parameters/endpoints: The primary outcome will be RBC potassium. 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 objective

1. Serum potassium in hemodialysis patients (CKD stage 5D) is mainly influenced by alterations in the internal potassium balance.
2. Higher dialysate potassium in CKD-5D increases the potassium erythrocyte concentration as proxy for TBK.

3. The increase in TBK by higher dialysate potassium reduces total body sodium stores in CKD-5D.

Study design

After 4 weeks of dialysis with dialysate solutions containing potassium either 2 mmol/L or 4 mmol/L there will be a study visit.

Intervention

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

Contacts

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Eligibility criteria

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
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-03-2019
Enrollment:	24
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

Ethics review

Positive opinion

Date:	20-03-2019
Application type:	First submission

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
NTR-new	NL7619
Other	METC AMC : METC2018_225

Study results