Renoprotective effects of potassium supplementation in chronic kidney disease

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To study the renoprotective effect of potassium supplementation in patients with CKD (stage 3b or 4 or estimated glomerular filtration rate [eGFR] 15 - 44 ml/min/1.73 m2).

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

Summary

ID

NL-OMON53024

Source
ToetsingOnline

Brief title
K+ in CKD

Condition

- Nephropathies

Synonym
Chronic kidney disease, chronic renal insufficiency

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Nierstichting

Intervention

Keyword: Albuminuria, Cardiovascular, Chronic kidney disease, Hypertension

Outcome measures

Primary outcome

2-year change in eGFR (renal outcome).

Secondary outcome

Effects on 24-hour blood pressure, albuminuria, cardiovascular markers, and

incidence of hyperkalemia

Study description

Background summary

Our current high-sodium, low-potassium diet lcontributes to the high prevalence of high blood pressure (hypertension). Indeed, the anti-hypertensive effects of potassium supplementation are well-established. Hypertension is even more prevalent and resistant in patients with chronic kidney disease (CKD) and contributes to further decline in kidney function. Four recent epidemiological studies (published 2014 - 2016) showed that higher dietary potassium intake was associated with better renal outcomes. All studies recommended an intervention study with potassium supplementation in patients with CKD.

Study objective

To study the renoprotective effect of potassium supplementation in patients with CKD (stage 3b or 4 or estimated glomerular filtration rate [eGFR] 15 - 44 ml/min/1.73 m2).

Study design

Multi-center clinical trial with open-label run-in phase (2 weeks, potassium chloride) followed by a double-blind placebo controlled intervention study (2 years, potassium chloride vs. potassium citrate vs. placebo).

Intervention

3 x 2 capsules (or 2 x 3 capsules) containing potassium chloride (40 mmol), potassium citrate (40 mmol) or placebo.

Study burden and risks

The study includes seven site visits with each one blood sample, 24-hour urine collection, spot urine collection, 24-hour blood pressure measurement, and pulse wave velocity measurement. Although these procedures are time-consuming and may be experienced as burdensome, they are all routine clinical studies and safe. Patients may experience a pill-burden (6 capsules/day). The open-label run-in phase is planned as a safety step to analyze which patients will develop hyperkalemia with potassium supplementation (they are excluded from the subsequent phase of the study). Hyperkalemia remains a risk during the 2-year double-blind intervention phase, but regular blood sampling and a specific algorithm if serum potassium levels rise, should prevent this. The potential benefits of the study are positive effects of potassium supplementation on blood pressure and kidney function.

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

- Adult patients with CKD stage 3b or 4
- Fall in eGFR > 2 ml/min/1.73 m2/year in preceding years
- Hypertension (automated blood pressure > 140/90 mmHg or use of anti-hypertensive medication)

Exclusion criteria

- Hyperkalemia (serum potassium > 5.5 mmol/l) at study visit V0
- Medical reasons to continue dual RAAS-blockade, mineralocorticoid receptor blockers, potassium-sparing diuretics, or oral potassium binders.
- Patients using calcineurin inhibitors
- Patients using tolvaptan
- Kidney transplant recipients
- Patients with an active gastro-intestinal ulcus
- Patients with previous history of ventricular cardiac arrhythmia
- Patients with a life expectancy < 6 months
- Expected initiation of renal replacement therapy < 2 years
- Incapacitated subjects or subjects who are deemed unfit to adequately adhere to instructions from the research team
- Women who are pregnant, breastfeeding or consider pregnancy in the coming 2 years.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2017
Enrollment:	532
Type:	Actual

Ethics review

Approved WMO Date:	29-06-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-04-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-03-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-09-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-10-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL60825.078.17