Explorative study to investige the acid-base response to five sodium and potassium salts in patients with chronic kidney disease (5Z study)

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Test the effect of five different sodium- and potassium salts in patients with chronic kidney disease.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Acid-base disorders
Study type	Interventional

Summary

ID

NL-OMON56418

Source
ToetsingOnline

Brief title
5Z study

Condition

- Acid-base disorders
- Nephropathies
- Vascular hypertensive disorders

Synonym
Acid-base disorder, acidification of the blood

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Chronic kidney disease, Electrolytes, Metabolic acidosis, Nephrology

Outcome measures

Primary outcome

Changes in plasma bicarbonate.

Secondary outcome

Effects on plasma potassium and chloride, acid-base parameters in urine and

plasma, blood pressure and body weight.

Study description

Background summary

The beneficial effect of potassium salt on kidney function, blood pressure and cardiovascular disease is becoming clearer, even for patients with chronic kidney disease. In a recent study we showed that suppletion with potassium chloride (to correct the dietary deficit) is well tolerated, but caused a mild hyperchloremic metabolic acidosis. Metabolic acidosis has detrimental effects and could therefore offset the potential effects of potassium. We think that chloride is responsible for this metabolic acidosis.

Study objective

Test the effect of five different sodium- and potassium salts in patients with chronic kidney disease.

Study design

Double-blind, placebo controlled randomized cross-over study with wash-out.

Intervention

Randomized treatment with potassium chloride, potassium bicarbonate, potassium gluconate, sodium chloride, sodium bicarbonate and placebo (6 x 5 days treatment followed by 2 days wash-out, the salts will be given via 3 x 3 capsules per day that in total contain 40 mmol potassium or sodium).

Study burden and risks

- 7 study visits in 6 weeks.
- At home daily blood pressure measurements, 3 times daily.
- Every study visit: 24-h urine collecetion (the day before), blood sample (4 tubes), urine portion and body weight measurement.
- Daily intake of 9 capsules (3 times per day 3 capsules)

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 (above 18 years) with CKD stage 3b or 4 (44 - 15 ml/min/1.73 m2)
Use of RAAS-inhibitors

Exclusion criteria

- Use of any of the following drugs or supplements: mineralocorticoid receptor blockers, potassium-sparing diuretics, oral potassium binders, immunosuppressive medication, tolvaptan, acetazolamide, topiramate, sodium bicarbonate. Patients using double RAAS blockade (i.e., ACE-inhibitor + ARB).
- Kidney transplant recipients
- Patients with an active gastro-intestinal ulcer
- Patients with previous history of ventricular cardiac arrhythmia
- Patients with a life expectancy < 6 months
- 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 7 weeks
- Patients with chronic respiratory acidosis in previous medical history

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-01-2024
Enrollment:	31

Type:	Actual

Ethics review

Approved WMO Date:	13-11-2023
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-09-2024
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	NL84462.078.23