Accurate Estimation of Sodium Intake with Limited Patient Burden

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The primary aim of this study is to assess whether repetitive morning, daytime or pre-night spot urine sampling can accurately estimate dietary Na+ intake and to determine the number of spot urine collections that are needed. We will assess whether...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON54047

Source
ToetsingOnline

Brief title
Sodium Balance Study

Condition

- Coronary artery disorders
- Renal disorders (excl nephropathies)
- Vascular hypertensive disorders

Synonym
chronic kidney failure, high blood pressure

Research involving
Human

Sponsors and support

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

Intervention

Keyword: estimation, intake, sodium, urine

Outcome measures

Primary outcome

The main outcome of this study is the difference between measured dietary Na+ and K+ intake and estimated Na+ and K+ intake, using multiple estimation methods.

We will compare the abovementioned outcomes in healthy individuals and individuals with chronic kidney disease.

Secondary outcome

We will compare methods for dietary Na+/K+ ratio estimation: single or repeated 24-hour measurement and single or repeated spot urine measurement. We will investigate the potential value of the urine Na+/K+ ratio as compared to separate urine Na+ and K+ measurements.

We will investigate the effects of correcting 24-hour Na+ and K+ excretion for 24-hour aldosterone and cortisol excretion.

We will compare the abovementioned outcomes in healthy individuals and individuals with chronic kidney disease.

Study description

Background summary

High sodium (Na+) intake is associated with worse cardiovascular and renal outcomes, whereas the contrary is observed when potassium (K+) rich diets are consumed. Because of this, patients with kidney and cardiovascular disease are advised to limit Na+ intake to 2 g/d. To monitor Na+ intake, patients collect 24-hour urine in which Na+ excretion is measured. This method is based on the assumption that 24-hour Na+ excretion equals 24-hour Na+ intake. Recent studies demonstrated that this assumption is false and that Na+ can be stored in and released from a newly discovered skin compartment. The use of 24-hour K+ excretion for estimation of K+ intake, although not commonly used, has also shown to be inaccurate. As a result, dietary advices to patients based on 24-hour urine collections are inadequate. We need improved urine-based methods for estimation of dietary Na+ and K+ intake, preferably with limited patient burden.

Study objective

The primary aim of this study is to assess whether repetitive morning, daytime or pre-night spot urine sampling can accurately estimate dietary Na+ intake and to determine the number of spot urine collections that are needed. We will assess whether using repetitive spot urine collection is superior to using a single 24-hour urine collection in estimating dietary Na+ intake. We will also explore this approach for K+ intake. The secondary objective is to define whether the dietary Na+/K+ ratio can be more accurately predicted than dietary Na+ or K+ intake separately, by measuring the urinary Na+/K+ ratio. If so, we will determine the number of spot and 24-hour urine collections that are needed for accurate estimation of the dietary Na+/K+ ratio. Further, we will assess whether Na+ or K+ intake estimation by 24-hour urine collection can be improved when Na+ or K+ excretion is corrected for aldosterone and cortisol excretion.

We will compare the abovementioned objectives between healthy participants and patients with chronic kidney disease, because Na+ measurements in the latter group can be influenced by medication use, kidney function and albuminuria.

Study design

This is an observational study. All study participants will receive a 14-day standardized diet, which will serve as a control for Na+ and K+ intake, containing a fixed amount of Na+ (157 mmol/day = 3600 mg/day) and K+ (85 mmol/day = 3300 mg/day).

Study burden and risks

Participants will need to collect all urine for 17 days and will follow a 14-day study diet Participants are urged to not conduct strenuous exercise

during the study. They will be instructed to keep daily documentation of consumed foods, beverages and diuresis. They will need to attend one 60-minute screening visit, three 30-minute study visits and four 15-minute study visits at our research facility. If desired, we will perform four home visits to replace the 15-minute study visits to lower the study burden. They will undergo a 10 mL blood draw twice.

Study insights will contribute to increased accuracy of urine-based Na+ and K+ intake estimation methods and may reduce patient burden. This will allow for better dietary advice on Na+ intake reduction, which will improve cardiovascular and renal outcomes. Using data from this study, we will develop a guideline on Na+ intake estimation in clinical 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

Healthy individuals: 18-80 years; eGFR above 60 ml/min/1.73m2 without albuminuria.

CKD patients: 18-80 years; eGFR 15-60 and/or albuminuria (albumine >30 mg/24h or albumine-creatinine ratio >3 mg/mmol).

Exclusion criteria

Healthy individuals: albuminuria; BMI > 30 kg/m2; office blood pressure > 140/90 mmHg; history of diabetes mellitus, hypertension, kidney disease, cardiovascular disease, restrictive dietary habits, eating disorders and/or food allergies; use of systemic glucocorticoids, antihypertensive and/or antidiabetic medication.

CKD patients: office blood pressure > 180/100 mmHg; suffering of acute kidney injury; changes in antihypertensive medication in the last 2 months; use of systemic glucocorticoids; dialysis treatment or expected initiation of dialysis within 3 months of screening; a history of restrictive dietary habits, an eating disorder or food allergies

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-04-2021
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	02-09-2020
Application type:	First submission
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	NL74313.018.20