Sodium balance study in healthy participants

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23937

Source
NTR

Brief title
SoBaS1

Health condition

Chronic kidney disease

Sponsors and support

Primary sponsor: Academic Medical Center
Source(s) of monetary or material Support: Dutch Kidney Foundation, grant number 19OP016

Intervention

Outcome measures

Primary outcome

The difference between measured and estimated dietary sodium, potassium and Na/K ratio intake, using:
- a single 24-hour urine collection

- repeated spot urine collections

Secondary outcome

For the most accurate estimation of dietary sodium, potassium and Na/K ratio intake, we will:
- compare the performance of 1, 3, 5 and 7 consecutive 24-hour urine collections
- compare the performance of 1, 3, 5 and 7 consecutive spot urine collections
- compare the performance of 1, 3, 5 and 7 consecutive spot urine collections with a single and repeated 24-hour urine collection

We will compare the performance of dietary sodium, potassium and Na/K ratio intake estimates based on:
- morning, daytime, pre-night and combined morning + pre-night spot urine collections
- different spot urine equations

Define the potential value of the urine Na/K ratio as compared to separate urine sodium and potassium measurements by comparing discrepancies (%) between:
- measured and estimated sodium intake
- measured and estimated potassium intake
- measured and estimated Na/K ratio

Investigate the effects of correcting 24-hour sodium and potassium excretion for 24-hour aldosterone and cortisol excretion, by determining:
- estimated sodium and potassium intake by correcting 24-hour urine sodium and potassium excretion for 24-hour urine aldosterone and cortisol excretion
- discrepancy (%) between measured and estimated sodium and potassium intake with and without correction for 24-hour urine aldosterone and cortisol excretion

Study description

Background summary

Backgroud
High sodium intake is associated with worse cardiovascular and renal outcomes, whereas the contrary is observed when potassium rich diets are consumed. Because of this, patients with kidney and cardiovascular disease are advised to limit sodium intake to 2 g/d. To monitor sodium intake, patients collect 24-hour urine in which sodium excretion is measured. This method is based on the assumption that 24-hour sodium excretion equals 24-hour sodium intake. Recent studies demonstrated that this assumption is false and that sodium can be stored in and released from a newly discovered skin compartment. The use of 24-hour potassium excretion for estimation of potassium 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 sodium and potassium intake, preferably with limited patient burden.

Design
This is an observational study. Healthy participants will receive a 14-day standardized diet, containing a fixed amount of sodium (157 mmol/day = 3600 mg/day) and potassium (85 mmol/day = 3300 mg/day). During the study all urine will be collected.

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

Study objective

We hypothesize that repeated spot urine sampling is non-inferior to a single 24-hour urine collection to estimate 24-hour dietary sodium and potassium intake.

Study design

Day -7, 0, 3, 6, 9, 12, 15, 18; however, study visits are flexible and will be scheduled based on the availability of participants

Intervention

n/a

Contacts

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Eligibility criteria

Inclusion criteria

• 18-80 years
• estimated glomerular filtration rate (eGFR) above 60 ml/min/1.73m2 as measured with the CKD-EPI equation without albuminuria (albumin >30 mg/24h or albumine-creatinine ratio >3 mg/mmol)

Exclusion criteria

• eGFR below 60 ml/min/1.73m2 as measured with the CKD-EPI equation or albuminuria (albumin >30 mg/24h or albumine-creatinine ratio >3 mg/mmol)
• office blood pressure > 140/90 mmHg
• diabetes mellitus, hypertension, kidney disease, cardiovascular disease
• use of antihypertensive medication, antidiabetic medication or systemic glucocorticoids
• (history of) restrictive dietary habits
• eating disorder
• food allergies

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2020
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	10-10-2020
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	NL9021
Other	METC AMC : METC 2020_141

Study results