Sodium balance study in healthy participants

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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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23937

Bron
NTR

Verkorte titel
SoBaS1

Aandoening

Chronic kidney disease

Ondersteuning

Primaire sponsor: Academic Medical Center
Overige ondersteuning: Dutch Kidney Foundation, grant number 19OP016

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

n/a

Contactpersonen

Publiek

Academisch Medisch Centrum
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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2020
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	10-10-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9021
Ander register	METC AMC : METC 2020_141

Resultaten