Lab-on-a-chip-based self-monitoring device for dietary Intake of Potassium and Sodium: an observational prospective comparative cohort study

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Primary: - To investigate the agreement between the lab-on-a-chip Medimate Minilab spot urine self-monitoring device and 24-hour urine collection for estimating past 24-hour dietary sodium intake for daily single and multiple self-tests by using the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vascular hypertensive disorders
Study type	Observational non invasive

Summary

ID

NL-OMON46440

Source
ToetsingOnline

Brief title
Lab-CHIPS study

Condition

- Vascular hypertensive disorders

Synonym
high blood pressure, hypertension

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W,CE Mate B.V.

Intervention

Keyword: Hypertension, Self-monitoring, Sodium, Urine

Outcome measures

Primary outcome

Variables: concentration sodium (mmol/L), potassium (mmol/L) en creatinine

(umol/L) in urine

Derived variables: Bland-Altman plot analyses with mean bias, 95% CI mean of

differences and 95% CI limits of agreement intervals and intervals of agreement

Outcome: agreement between two diagnostic tests

Secondary outcome

same as primary

Study description

Background summary

Cardiovascular diseases is the leading cause of death globally. Hypertension is the biggest risk factor for the development of cardiovascular disease and also chronic kidney disease. Unfortunately the control rates of hypertension remain poor, only 33% is adequately controlled. Taking into account the growing prevalence of hypertension there is much need to improve our treatment strategies. Lifestyle modification is a crucial part of hypertension treatment. Dietary adjustments are one of those modifications. This includes for instance reducing sodium intake and upholding enough potassium rich food consumption. Current guidelines recommend intake of <6.0 grams of salt (sodium-chloride) a day. For potassium, >3.5 grams a day for men and >3.1 grams a day for women is recommended. Average salt consumption in the Netherlands between 2006 and 2015 is still very high: men use on average 9,7 grams a day, women 7,4 grams a day. Potassium intake is just above the recommended level, with selected population groups still at risk. The gold standard for determining dietary sodium and

potassium intake consists of 24 hour collection of urine at home, transport to the hospital, analysis by a clinical chemist and patient feedback by the treating physician. This method is prone to collection error, cumbersome and time consuming. It also only shows the dietary estimated intake of sodium and potassium from 1 day and is therefore not representative of a person*s actual average intake.
CE-Mate B.V., in cooperation with UMC Utrecht, have developed an innovative lab-on-a-chip self-test device that uses microchip capillary electrophoresis (µCE) to measure sodium, potassium and creatinine levels in a single drop of urine. This can be done at home. These values can be used to estimate past 24 hour dietary sodium and potassium intake. For the first time, this provides the patient with before absent insightfulness in real time daily dietary intake of sodium and potassium. Thereby subsequently stimulate lifestyle modification through self-management and self-empowerment (greater involvement in their own treatment). The method of self-empowerment is proven to be effective in stimulating adherence to important lifestyle modifications. In conclusion our medical validation study aims to investigate the agreement of a new self-test device to estimate past 24 hour sodium and potassium intake versus the current gold standard of 24 hour urine collection and analysis.

Study objective

Primary:
- To investigate the agreement between the lab-on-a-chip Medimate Minilab spot urine self-monitoring device and 24-hour urine collection for estimating past 24-hour dietary sodium intake for daily single and multiple self-tests by using the Intersalt, Kawasaki and Tanaka formulae

Secondary:
- To investigate the agreement between the lab-on-a-chip Medimate Minilab spot urine self-monitoring device and 24-hour urine collection for estimating past 24-hour dietary potassium intake for daily single and multiple self-tests by using the Intersalt, Kawasaki and Tanaka formulae

- To investigate the agreement between the Medimate Minilab performed multiple spot urine self-tests and 24-hour urine collection for estimating dietary sodium weekly average by using the Intersalt, Kawasaki and Tanaka formulae formula.

- To investigate the agreement between the Medimate Minilab performed multiple spot urine self-tests and 24-hour urine collection for estimating dietary potassium weekly average by using the Intersalt, Kawasaki and Tanaka formulae formula.

- To investigate agreement between the lab-on-a-chip Medimate Minilab spot urine self-monitoring device and 24-hour urine collection for estimating past

24-hour dietary sodium-to-potassium ratio for single and multiple self-tests

- To Investigate the agreement between the Medimate Minilab performed multiple spot urine tests and 24-hour urine collection for estimating dietary sodium-to-potassium ratio weekly average.

Study design

Observational prospective comparative cohort study

Study burden and risks

Risk analyses: low, no further comments

Burden participants:
- test subjects are asked to collect and analyse their own urine samples participate for 3 weeks and 1 day in total
- in total per test subject: 3 times 24 hour urine collection, 31 times spot urine collection and analysis.
- time investment: 3x times 24 hour urine collection,31 times, once a day and every 7 days 4 times a day, 10-15 minute urine sample collection and self testing. Self testing consists of estimated maximum 3-5 minutes self test preparations and 8 minute automatic measurement of the Medimate Minilab device. Measurements will be recorded and stored automatically.
- Urine transport and drop-off at the lobaratory site estimated 1 hour per week (3 hours in total). Introduction, information and instruction meeting at the start of the study: 1,5 hour in total.

- Test subjects are asked to uphold a certain diet during 3 weeks. 3 different diets, 1 per week. 1 week will be liberal (own eating habits), 1 week we will ask the subjects to eat less than 8 grams of salt a day, 1 week we will ask them to eat > 12 gram a day. Instructions on how to uphold these diets will be given during a scheduled introduction meeting. Also test subjects will be given written instructions how to best adhere to dietary advice, setup in cooperation with our nutrition and dietetics department.

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 motivated volunteers
- Age >18
- Man or woman
- Dutch, English native language
- Motivated for performing daily self-tests

Exclusion criteria

any known medical history of: any kind of cardiovascular disease e.g. stroke, heart failure, myocardial infarction, aortic dilatation of any kind, uncontrolled hypertension (3 or more antihypertensive medications, blood pressure Systolic>160; diastolic >90mmHg), renal disease or renal insufficiency, incontinence, impaired vison, diet restrictions for other medical reasons. Pregnancy. Measured Blood pressure of >140/85mmHg at inclusion screening examination.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-06-2018
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	14-03-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL63079.041.17