Determinants of salt taste in healthy volunteers and patients with chronic kidney disease

Published: 01-12-2020
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To compare salt taste and saliva characteristics in healthy volunteers and patients with CKD.

Ethical review	Approved WMO
Status	Pending
Health condition type	Nephropathies
Study type	Observational invasive

Summary

ID

NL-OMON55173

Source
ToetsingOnline

Brief title
Human salt taste

Condition

- Nephropathies

Synonym
chronic kidney disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Chronic kidney disease, Salt sensitivity, Salt taste

Outcome measures

Primary outcome

Salt-sensitivity (as determined by salt taste testing), 24-hour blood pressure, 24-hour urinary excretion of sodium, plasma renin and aldosterone concentrations.

Secondary outcome

- To correlate salt sensitivity thresholds to blood pressure, plasma renin and aldosterone levels.

- To correlate salt sensitivity thresholds to differences in the salivary proteome.

- To correlate salt sensitivity thresholds to the ability to activate ENaC in a heterologous expression system (Xenopus oocytes).

Study description

Background summary

High dietary salt (NaCl) intake is one of the root causes of the high blood pressure pandemic that drives premature cardiovascular and renal morbidity and mortaility. There is a clear link between high dietary salt intake and these pathalogical outcomes, but surprisingly little is known about human salt taste in health and disease. Patients suffering from chronic kidney disease (CKD) are charecterised by impaired salt taste which results in an even higher dietary salt intake. It is known that epithelial sodium channels (ENaC) in the tongue mediate salt taste. These channels can be cleaved via proteolytic cleavage as is known from studies looking at ENaC in the kidney. Additionally, the salivary proteome of healthy (salt-senisitive) subjects was shown to be enriched for proteases, whereas CKD patients (salt-resistant) had more protease inhibitors. With this study, we would like to explore wheter ENaC in the tongue are

proteolytically modulated by proteases in saliva, and if the high concentration of protease inhibitors found in salt-resistant subject is responsible for the reduced salt taste.

Study objective

To compare salt taste and saliva characteristics in healthy volunteers and patients with CKD.

Study design

Observational study in which we will determine salt taste and collect saliva samples in healthy subjects and CKD patients (n=20/group). The two groups will be matched according to age and gender.

Study burden and risks

The study will consists of 3 study visits with 3x salt taste testing, 3x saliva sample collections, 1x 24-hour urine collection, 1x 24-hour blood pressure measurement, and 1x blood collection. These procedures may cause discomfort. If patients use anti-hypertensive drugs that interfere with salt taste, the measurements will be performed twice (with and without medication), resulting in 6 study visits. During drug discontinuation, home blood pressure will be monitored and (non-interfering) escape medication will ben provided, if necessary.

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

The patient group:
- Adult (>= 18 years)
- CKD (eGFR 15-44 ml/min/1.73 m2)

The group of healthy volunteers:
- Adult (>= 18 years)

Exclusion criteria

The exclusion criteria for the CKD patients:
- smoking
- any mouth disease
- Diabetes mellitus
- Use of any of the following drugs: clopidogrel, amiodaron, flecainide, sotalol, propafenon.
- intellectual disability

The exclusion criteria for the healthy volunteers:
- smoking
- any mouth disease
- Hypertension (difined as office blood pressure > 140/90 mmHg)
- Reduced eGFR, albuminuria, or a known kidney disease
- Diabetes mellitus
- Intellectual disability

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2021
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO Date:	01-12-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	27-10-2021
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	NL74395.078.20