Ammonium chloride test and distal urine acidification

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to determine if there is an alternative mechanism for urine acidification in men in response to NH4Cl other than that through ENaC

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Renal disorders (excl nephropathies)
Study type	Observational invasive

Summary

ID

NL-OMON44170

Source
ToetsingOnline

Brief title
Distal urine acidification

Condition

- Renal disorders (excl nephropathies)

Synonym
renal tubular disorders

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: subsidie college zorgverzekeraars

Intervention

Keyword: ammonium chloride test, ENaC, urine acidification

Outcome measures

Primary outcome

urine pH in response to NH4Cl with and without amiloride

Secondary outcome

n/a

Study description

Background summary

Distal renal tubular acidosis (dRTA) can be diagnosed using NH4Cl loading or the furosemide fludrocortisone test (FF test). Recent reports show discrepant results between the NH4Cl test and the FF test. About 30% of patients with suspected dRTA show a normal decrease of urine pH after NH4Cl but a disturbed FF test.

Study objective

to determine if there is an alternative mechanism for urine acidification in men in response to NH4Cl other than that through ENaC

Study design

an intervention study in which 10 healthy volunteers will undergo two NH4Cl tests on separate days: one without and the other under treatment with the ENaC blocker amiloride which is given at two moments during the test.

Study burden and risks

The total number of blood samples is 2 per test. The total number of urine samples is 8 per test. The risks of the study are negligible. Oral intake of NH4Cl can cause bad taste and nausea/vomiting.

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 8
Nijmegen 6500 HB
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 8
Nijmegen 6500 HB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

age > 18 years old

Exclusion criteria

any medical history
inability to give informed consent
pregnancy
medication use (except for oral contraceptives)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-12-2017
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	01-11-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL62691.091.17