

# 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 NH<sub>4</sub>Cl other than that through ENaC

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Renal disorders (excl nephropathies)
<b>Study type</b>	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 NH<sub>4</sub>Cl with and without amiloride

### Secondary outcome

n/a

## Study description

### Background summary

Distal renal tubular acidosis (dRTA) can be diagnosed using NH<sub>4</sub>Cl loading or the furosemide fludrocortisone test (FF test). Recent reports show discrepant results between the NH<sub>4</sub>Cl test and the FF test. About 30% of patients with suspected dRTA show a normal decrease of urine pH after NH<sub>4</sub>Cl but a disturbed FF test.

### Study objective

to determine if there is an alternative mechanism for urine acidification in men in response to NH<sub>4</sub>Cl other than that through ENaC

### Study design

an intervention study in which 10 healthy volunteers will undergo two NH<sub>4</sub>Cl 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 NH<sub>4</sub>Cl can cause bad taste and nausea/vomiting.

## Contacts

### Public

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## **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**

CCMO

**ID**

NL62691.091.17