

Urine acidification in men

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

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|------------------------------|------------------------|
| Ethical review | Approved WMO |
| Status | Recruitment stopped |
| Health condition type | Nephropathies |
| Study type | Observational invasive |

Summary

ID

NL-OMON42942

Source

ToetsingOnline

Brief title

Urine acidification in men

Condition

- Nephropathies

Synonym

renal tubular disorders

Research involving

Human

Sponsors and support

Primary sponsor: Radboud Universiteit Nijmegen

Source(s) of monetary or material Support: subsidie college zorgverzekeringen

Intervention

Keyword: furosemide fludrocortison test, NHE3, Urine acidification

Outcome measures

Primary outcome

urine pH in response to furosemide and fludrocortison with and without
amiloride

Secondary outcome

none

Study description

Background summary

Distal renal tubular acidosis is often diagnosed using NH_4Cl loading. More recently this test has been replaced by the furosemide fludrocortison test (FF test). The FF test is based on the classical mechanism that furosemide induces distal tubular sodium delivery and fludrocortison further enhances sodium re-absorption through ENaC and secondly H^+ secretion through H^+ -ATPase/ H^+ - K^+ -ATPase in the collecting duct. In mice however, furosemide can also acidify urine by stimulating the Na^+ - H^+ transporter NHE3 and hereby Na^+ reabsorption and H^+ excretion. If such a mechanism is present in men as well, the FF test could result in normal urinary acidification in patients with dRTA.

Study objective

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

Study design

an intervention study in which 10 healthy volunteers will undergo two furosemide fludrocortison tests on separate days: one without and the other after pre-treatment with the ENaC blocker amiloride (10 mg) which is given 2 hours before the start of the test.

Study burden and risks

The total number of blood samples is 3 per test. The total number of urine samples is 5 per test. The risks of the study are negligible.

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

age * 18 years old

Exclusion criteria

any medical history

inability to give informed consent

pregnancy

medication use (except for oral anti contraceptives)

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 13-09-2016

Enrollment: 10

Type: Actual

Ethics review

Approved WMO

Date: 01-09-2016

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 | NL57365.091.16 |