Renal tubular function tests

Published: 27-10-2015
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to develop standardized tubular function tests with reference intervals/values.

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

Summary

ID

NL-OMON41969

Source
ToetsingOnline

Brief title
Renal tubular function tests

Condition

- Nephropathies

Synonym
disorder fo the renal tubules, renal tubular disorders

Research involving
Human

Sponsors and support

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

Intervention

Keyword: electrolytes, renal functioon, renal tubule, test

Outcome measures

Primary outcome

Standardized operating procedures with reference values for the following

tubular function tests: hydrochlorothiazide test, furosemide test, DDAVP test

and furosemide-fludrocortison test.

Secondary outcome

not applicable

Study description

Background summary

Electrolyte disorders can be the consequence of acquired or inherited renal tubular defects. Most often, these abnormalities are explained by malfunctioning of the channels or transporter proteins that are critically involved in the transport of the electrolytes. These tubular disorders are rare, and mostly knowledge about validated clinical diagnostic tools is lacking. These tubular function tests on the other hand are very helpful in the understanding of (an) underlying defect(s) and can help directing more specific and expensive diagnostic tests and direct therapy.
In this study we will therefore determine reference values for tubular function tests for which we have developed standard operating procedures (SOP*s) for. The aim of this study is to develop standardized tubular function tests with reference intervals/values. In the future, these tubular function test can be used in clinical practice to investigate the underlying tubular defect in a patient with an unknown tubular disease or to relate phenotype and genotype in special patient groups.

Study objective

to develop standardized tubular function tests with reference intervals/values.

Study design

This is an observational study in which several tubular function tests (furosemide test, hydrochlorothiazide test, DDAVP test and

furosemide-fludrocortisone test) will be performed in a group of volunteers. These individuals will differ in age and glomerular filtration rate. The tests will be performed in the Radboud University Hospital by a group of trained nurses at our well equipped dialysis unit.

Study burden and risks

Adverse reactions occurring most often (but still infrequently) with furosemide and hydrochlorothiazide include hyponatremia, hypokalemia, hypovolemia and hypotension.
Adverse reactions occurring most often (but still infrequently) with fludrocortison include hypertension, edema, hypokalemia and heart failure.
Adverse reactions occurring most often (but still infrequently) with desmopressin include headache, nausea and flushing along with mild abdominal cramps. Desmopressin should be used with caution in patients with fluid and electrolyte inbalances such as heart failure and concomitant administration of tricyclic antidepressants/NSAID*s/carbamazepine.
Patients will therefore be observed for signs or symptoms associated with hyponatremia (headache, nausea/vomiting, restlessness, fatigue, lethargy, disorientation, confusion) and heart failure (shortness of breath).
Furthermore, body weight, blood pressure and heart rate will be recorded and a blood gas will be drawn at the end of the test for fast determination of potassium and sodium.

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

- inability to give informed consent
- pregnancy
- severe heart failure
- electrolyte disorder (sodium, potassium)
- renal disease
- hypertension
- proteinuria

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):	26-01-2016

Enrollment:	110
Type:	Actual

Ethics review

Approved WMO Date:	27-10-2015
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	NL52460.091.15