AC/DC Study: Acidification test in patients with Chronic kidney Disease and healthy Controls

Published: 07-10-2016
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To measure changes in urinary RAS components during an acid-loading test in patients with CKD and healthy controls.

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

Summary

ID

NL-OMON42898

Source
ToetsingOnline

Brief title
AC/DC study

Condition

- Nephropathies

Synonym
chronic kidney disease, chronic renal insufficiency

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Netherlands Foundation for Cardiovascular excellence

Intervention

Keyword: Acidification test, Chronic kidney disease, Renin-angiotensin system

Outcome measures

Primary outcome

The primary study parameter is the change in urinary renin values (an accepted

measure of intrarenal RAS activity).

Secondary outcome

Not applicable

Study description

Background summary

Metabolic acidosis is one of the metabolic complications of chronic kidney disease (CKD). Correction of metabolic acidosis in CKD has been shown to prevent further loss of kidney function over time. Currently, we are conducting a clinical trial (the BIC-study, MEC-2013-332) in which patients with CKD and metabolic acidosis receive sodium bicarbonate, sodium chloride, or no treatment (time control) to address the hypothesis that the beneficial effects of acidosis correction are mediated through inhibition of the intrarenal renin-angiotensin system (RAS). It is unknown, however, if and how acute changes in acid-base status affect the intrarenal RAS during CKD. In the present study we hypothesize that an acute acid load increases the activity of the intrarenal RAS, and that this response is exaggerated in patients with CKD compared with healthy controls.

Study objective

To measure changes in urinary RAS components during an acid-loading test in patients with CKD and healthy controls.

Study design

Diagnostic test

Intervention

All participants will undergo a urinary acidification test with ammonium chloride.

Study burden and risks

All subjects will receive ammonium chloride (100 mg/kg body weight, given orally) during a single-day hospital admission. For blood drawing a catheter will be inserted in a forearm vein. The test requires 3 venous blood collections and collection of all urine produced over the course of 8.5 hours. Oral ammonium chloride can cause abdominal discomfort and nausea (0-10%), and in some cases vomiting (0-6%). Venous catheter placement might cause physical discomfort. There is a very small risk of infection (thrombophlebitis) or hematoma at the puncture place.

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

Patients with CKD:
- Male or female adults (*18 years)
- Chronic kidney disease stage 4 (eGFR: 15-30 ml/min/1.73 m2)
Healthy subjects:
- Healthy male or female adults (* 18 years)
- Normal kidney function (eGFR > 90 ml/min/1.73 m2)

Exclusion criteria

Patients with CKD:
- Plasma bicarbonate level < 20.0 mmol/l
- Serum potassium >5.5 mmol/l
- Sodium bicarbonate use in the month preceding the study
- Heart failure (NYHA III or IV)
- Liver cirrhosis (Child Pugh B or C)
- Blood pressure >140/90 mmHg despite the use of 3 different anti-hypertensives
- Kidney transplantation
- Use of calcineurin inhibitors
- Known urea cycle disorder
- Alcoholism or drug use
- Pregnancy
- Current use of antibiotics, NSAIDS or alkalizing drugs (sodium-bicarbonate, citric acid, potassium citrate, acetazolamide)
- Inability to adhere to the study protocol (due to language barrier or intellectual disability);Healthy subjects:
- eGFR < 90 ml/min/1.73 m2
- plasma bicarbonate < 20 mmol/l.
- History of, or drugs for, diabetes mellitus
- History of chronic diarrheal disease
- Ileostomy/colostomy
- Known urea cycle disorder
- Alcoholism or drug use
- Pregnancy
- Current use of antibiotics, antihypertensive drugs, NSAIDS or alkalizing drugs
- Inability to adhere to the study protocol (due to language barrier or intellectual disability)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-03-2017
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO

Date:	07-10-2016
Application type:	First submission
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	NL57148.078.16