Distal renal tubular acidosis in primary Sjögren syndrome

Published: 07-06-2013
Last updated: 25-04-2024

This study has two main objectives:• to evaluate the prevalence of dRTA in pSS using the urinary acidification test with FF and compare this against the gold standard test with AMCL.• to evaluate whether a low BMD is more prevalent in patients with...

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

Summary

ID

NL-OMON39002

Source
ToetsingOnline

Brief title
dRTA in pSS 2

Condition

- Autoimmune disorders
- Bone disorders (excl congenital and fractures)
- Renal disorders (excl nephropathies)

Synonym
type 1 RTA, urinary acidificaiton problem localized in the kidney

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Distal renal tubular acidosis (dRTA) primary Sjögren syndrome (pSS), Urinary acidification test

Outcome measures

Primary outcome

The main endpoint of this study is to determine the prevalence of dRTA in pSS

using two acidification tests. Additionally, the prevalence of an abnormal BMD

will also be determined in the same group.

Secondary outcome

Secondary endpoint of this study is the calculation of the sensitivity and

specificity of the FF test.

Study description

Background summary

The association between dRTA and pSS has been described in various case reports. It is unclear what the true prevalence of dRTA in pSS is. A study which used the two available urinary acidification tests, the ammonium chloride test and the furosemide/fludrocortisone test, to analyze the prevalence of dRTA in a large group of pSS patients is lacking. Furthermore, the prevalence of complications of dRTA is unclear. As described above, dRTA can lead to a low bone mineral densitiy and kidney stones, which are serious complications.

Assessment of the exact prevalence of dRTA and its complications is important because there is an effective treatment for both the symptoms and complications of dRTA. Additionally, this study provides us the possibility to calculate the sensitivity and specificity of the furosemide/fludrocortisone test which can lead to an altered diagnostic algorithm for dRTA.

Study objective

This study has two main objectives:

• to evaluate the prevalence of dRTA in pSS using the urinary acidification

test with FF and compare this against the gold standard test with AMCL.

• to evaluate whether a low BMD is more prevalent in patients with dRTA in pSS compared to patients without dRTA in pSS

This study has one secondary objective:

• To calculate the sensitivity and specificity for the FF test to diagnose dRTA.

Study design

The current study is designed as an observational study with invasive measurements. All participants will be seen twice in the hospital, with minimal one week in between. On the first day, all participants will undergo the AMCL loading test and on the second day the FF test will be performed. During the time they are in the hospital, a DEXA scan will be performed.

This study design provides us results of both urinary acidification tests performed in our target population. Additionally, performing a DEXA scan in all participants will give us information whether low BMD is more prevalent in pSS patient with dRTA as compared to those without.

Study burden and risks

This project is expected to determine the prevalence of dRTA in pSS and its major complication, which is low BMD. Many patients with pSS have complaints of fatigue and generally feel unwell. The presence of dRTA may be a potentially treatable explanation of these complaints in some patients. Additionally, the clinical relevance of both tests will be calculated.
Prior to the study, if applicable, treatment with potassium citrate should be stopped. The participants have to be hospitalized for two days. The urinary acidification test with FF has no reported side-effects, but the acidification test with AMCL can cause temporarily abdominal pain and nausea. The DEXA scan has a negligible radiation load. Although the tests are safe, all participants are insured for adverse events.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
Rotterdam 3015CE

NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
Rotterdam 3015CE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

The pSS patients have to meet the following inclusion criteria:
• Age older than 18 years
• Diagnosis based on the Revised international classification criteria for Sjögren syndrome
• No secondary auto-immune disease (SLE, Rheumatoid Arthritis)

Exclusion criteria

The exclusion criteria are also mentioned in the inclusion criteria.

Study design

Design

Study type: Observational invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-06-2013
Enrollment:	62
Type:	Actual

Ethics review

Approved WMO

Date:	07-06-2013
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	NL43758.078.13