Distal renal tubular acidosis in Sjögren syndrome

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

Summary

ID

NL-OMON39423

Source
ToetsingOnline

Brief title
dRTA by Sjögren syndrome

Condition

- Autoimmune disorders
- Nephropathies

Synonym
renal tubular acidosis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: eigen middelen + kleine subsidie Kolff beurs

Intervention

Keyword: acidification test, calcium metabolism, dRTA, Sjögren syndrome

Outcome measures

Primary outcome

The presence of dRTA and/or disorders in calcium metabolism and if present the

underlying pathogenetic mechanism.

Secondary outcome

not applicable

Study description

Background summary

Sjögren syndrome (SS) is associated with distal renal tubular acidosis (dRTA). The true prevalence of dRTA in patients with SS is unclear. dRTA is associated with osteoporosis and kidney stone formation and a poor well-being of the patient. There is an effective treatment for dRTA so screening for dRTA in patients with SS is necessary.

Study objective

The objectives of this study are to determine the prevalence of dRTA, osteoporosis and nephrolithiasis in patients with SS. We also try to elucidate the mechanism which is responsible for developing dRTA in patients with SS. The role of auto antibodies against carbonic anhydrasis type II and the M3-receptor will be considered.

Study design

The study is an observational study. All participants will be hospitalized during a half day.

Study burden and risks

There are no risks for the participant by participating this study. There are no adverse events described by the used urinary acidification test.

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 fullfilling the criteria of the Revised International classification criteria for Sjögren syndrome with Sjögren syndrome
A healthy controlgroup
Age >20 years

Exclusion criteria

Hypokalemia prior to the test
Age < 20 years

Study design

Design

Study type:	Observational invasive
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):	01-02-2012
Enrollment:	97
Type:	Actual

Ethics review

Approved WMO Date:	25-01-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-06-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-05-2013
Application type:	Amendment
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	NL37422.078.11