Distal renal tubular acidosis in Sjögren Syndrome and postmenopausal osteoporosis

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Ethical review	Not approved
Status	Will not start
Health condition type	Autoimmune disorders
Study type	Observational non invasive

Summary

ID

NL-OMON36946

Source
ToetsingOnline

Brief title
dRTA in pSS and osteoporosis

Condition

- Autoimmune disorders
- Bone disorders (excl congenital and fractures)
- 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: Distal renal tubular acidosis, Osteoporosis, Sjögren syndrome, Urinary acidification test

Outcome measures

Primary outcome

We intend to determine the prevalence of dRTA and/or disorders in calcium

metabolism in pSS and postmenopausal osteoporosis. Additionally, we intend to

study the underlying pathogenetic mechanism. The results of alkali treatment

will be monitored.

Secondary outcome

na

Study description

Background summary

Primary Sjögren syndrome (pSS) is associated with distal renal tubular acidosis (dRTA). However, the prevalence of dRTA in patients with pSS is unclear. DRTA is associated with disorders in calcium metabolism, osteoporosis and kidney stone formation and a poor well-being of the patient. Osteoporosis is diagnosed in 7% of the population, but numbers about dRTA being the underlying cause is lacking.
As there is an effective treatment for dRTA, screening for dRTA in patients with pSS and postmenopausal osteoporosis seems warranted.

Study objective

The aims of the present study are 1) to confirm the high prevalence of dRTA in Sjögren using the urinary acidification test with ammonium chloride, 2) to determine the prevalence of disorders in calcium metabolism in pSS patients with dRTA, 3) to investigate the association of dRTA with auto-antibodies against carbonic anhydrase type II (CA II) and the M3-receptor, 4) to assess the association of altered expression of acid-base expression in urinary

exosomes, 5) to evaluate whether dRTA is more prevalent than currently thought in postmenopausal osteoporosis using a new screening test with furosemide and fludrocortisone and compare this against the gold standard test with ammonium chloride and 6) to assess the effects of alkali treatment with special attention to the BMD, serum calcium and potassium levels and bone markers and urinary excretion of calcium and citrate

Study design

The study is an observational study. In all 33 subjects with an abnormal screening test using fludrocortisone and furosemide we will repeat this test and additionally perform an acidification test using ammonium chloride. Furthermore, if not performed within the preceding year, all 33 subjects will undergo an ultrasound examination of the kidneys and a DEXA-scan.
The 105 subjects in the control group will undergo an ultrasound examination and a DEXA-scan. They will also undergo the screenings test for dRTA by using the furosemide/fludrocortisone acidification test, to rule out dRTA as the underlying cause of osteoporosis in our control group.
All 38 cases of postmenopausal osteoporosis will first undergo the screening test by using the furosemide/fludrocortisone test. Patients with an abnormal screening test will undergo the follow-up as described above.

Study burden and risks

All 33 subjects will be seen twice, with minimal one week in between. The 105 control subjects will undergo both radiographic examinations and the screenings test on one day. Urine and blood will be collected from all 33 subjects. Mild adverse effects (nausea, vomiting) are described after ammonium chloride loading. DEXA scanning leads to a negligible radiation load.
All 38 patients with postmenopausal osteoporosis will be seen once to evaluate the presence of dRTA. Patients with an abnormal test, will be seen twice more to confirm dRTA.

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

Diagnosed with postmenopausal osteoporosis
Diagnoses of Sjögren syndrome based on American-Europenean criteria
DEXA-scan performed within the last year
DEXA-scan with a T-score < -2,5
Age older than 18 years
No secondary cause known of osteoporosis
No previous record of urinary pH screening

Exclusion criteria

Secondary osteoporosis
Age below 18
DEXA-scan with T > -2,5

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	176
Type:	Anticipated

Ethics review

Not approved

Date:	20-12-2012
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	NL42434.078.12