The pathogenesis of vaginal dryness in women with primary Sjögren*s syndrome: a pilot study

Published: 23-04-2015
Last updated: 14-04-2024

Objective: Primary: To evaluate whether the vaginal mucosa of women with pSS shows histological signs of local inflammation. Secondary: A) To evaluate whether levels of pSS-related autoantibodies, (pro-inflammatory) cytokines and cellular markers,...

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

Summary

ID

NL-OMON44049

Source
ToetsingOnline

Brief title
Vaginal dryness in primary Sjögren's syndrome

Condition

- Autoimmune disorders

Synonym
Sjögren's syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Reumafonds

Intervention

Keyword: Autoimmune, Pathogenesis, Sjögren's syndrome, Vaginal dryness

Outcome measures

Primary outcome

Immunohistochemistry of vaginal and endocervical mucosa

Secondary outcome

- Immunological parameters in the vagina, e.g. the local expression of

chemokines and cytokines in the vaginal and cervical tissue and secretions.

- Gynaecological parameters, e.g. the vaginal health index (VHI)

- Clinical disease parameters, e.g. disease activity

- patient reported parameters, e.g. sexual function, vaginal complaints,

patient reported symptoms of pSS

Study description

Background summary

Primary Sjögren*s Syndrome (pSS) is a common systemic autoimmune disease, which is characterized by chronic inflammation of salivary and lacrimal glands, resulting in dryness of the eyes and mouth. Dryness complaints are, however, not restricted to these exocrine glands and women with pSS also suffer from vaginal dryness. Vaginal dryness in pSS can cause discomfort in daily life, an increased risk of vaginal infections and sexual dysfunction. Very little data is available on the pathogenesis of vaginal dryness in pSS. Possible explanations for the vaginal dryness in pSS are the presence of vasculitis or epitheliitis of the vaginal mucosa, or cervicitis.

Study objective

Objective: Primary: To evaluate whether the vaginal mucosa of women with pSS shows histological signs of local inflammation.
Secondary:
A) To evaluate whether levels of pSS-related autoantibodies, (pro-inflammatory)

cytokines and cellular markers, related to inflammation, are elevated in vaginal secretions of patients with pSS.
B) To evaluate whether women with pSS have impaired vaginal health, infectious vaginitis, bacterial vaginosis or atrophic vaginitis.
C) To evaluate whether inflammation of the vaginal mucosa is associated with systemic and patient reported disease activity in pSS.
D) To evaluate whether inflammation of the vagina is associated with vaginal sicca symptoms and sexual dysfunction.

Study design

Case-control pilot study

Study burden and risks

Patients will be asked to bring 1 extra visit to the UMCG. Healthy controls Controls will not have to pay any extra visits to the UMCG. Participants will be asked to undergo gynaecological evaluation with collection of vaginal samples (15 min) and to fill in a questionnaire (20 min). In addition, patients will be asked to undergo an rheumatological evaluation of disease activity, during which a history is taken and physical examination is done (45 min). Participation in this study involves two minor invasive procedures: vaginal and cervical biopsy (in patients and controls), and venapunction (only in patients). The vaginal and cervical biopsy is a safe procedure without major risks, but might cause some bleeding or discharge. The inconvenience of this procedure will be minimalised by using local anesthesics in patients and performing the procedure under total anaesthesia in healthy controls who undergo RRSO. For the control group, women will be selected who are scheduled to undergo a surgical or diagnostic gynaecological procedure such as risk-reducing salpingo-oophorectomy (RRSO), diagnostic laparoscopy, laparoscopic sterilization or other (minor) surgical procedures, and who do not have any auto-immune, inflammatory or infectious disease of the cervix or vagina. In patients one extra venapunction is done, during which 27 ml of blood is collected. In healthy controls, an extra 8,5 ml of blood will be drawn during a routine venapunction. Venapunction is also a very safe procedure but might cause some bruising. Patients will be asked to collect a urine portion. Participants will not experience direct benefits of participation in this study. However, this pilot study will provide a basis for further research into the pathogenesis of vaginal sicca symptoms in pSS and give direction to the development of a better treatment for this complaint. At the moment, local and systemic treatment options for vaginal dryness are insufficient, and there is a need for research on the topic of vaginal dryness as part of Sjögren*s syndrome. Therefore, we believe the advantages of participation outweigh the burden and risk associated with participation.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700 RB
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700 RB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients:
• Diagnosis of pSS according to the American European Consensus Group (AECG) classification criteria.
• Presence of vaginal sicca symptoms ;All participants:
• Female gender
• Age >=18
• Premenopausal status according to the World Health Organisation definition.
• Written informed consent

Exclusion criteria

• Presence of other systemic autoimmune disease
• Use of systemische corticosteroids within 1 month before inclusion.
• Use of disease modifying anti-rheumatic drugs (DMARDs), except hydroxychloroquine, within 1 month before inclusion.
• Use of biological DMARDs within 6 months before inclusion.
• Use of hormone replacement therapy or use of vaginal oestrogen supplementation
• Use of a intrauterine contraceptive device
• Pregnancy
• Presence of a known infectious or non-infectious inflammatory disorder of the vagina or cervix (e.g. lichen sclerosis or lichen planus of the vagina, sexually transmitted infections)
• Other gynaecological or non-gynaecological comorbidity which is expected to influence the vaginal or cervical health and/or gynaecological immune markers according to the investigators, including previous chemotherapy.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-12-2015
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	23-04-2015

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	14-02-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL52349.042.15

Study results

Date completed:	25-09-2017
Actual enrolment:	20