Vaginal dryness and sexuality in primary Sjögren*s syndrome: A cross-sectional study

Published: 27-03-2013
Last updated: 23-04-2024

Primary objective: To evaluate the influence of pSS on sexual function, as measured by the female sexual function index (FSFI), in comparison to a healthy control group. Secundary objective: To evaluate the influence of pSS on subdomains of sexual...

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

Summary

ID

NL-OMON38515

Source
ToetsingOnline

Brief title
Vaginal dryness and sexuality in primary Sjögren's syndrome

Condition

- Autoimmune disorders

Synonym
(no layman's term available), Primary Sjögren Syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Sjögren werkgroep van het UMCG

Intervention

Keyword: Sexuality, Sjögren's syndrome, Vaginal dryness, Vaginal sicca symptoms

Outcome measures

Primary outcome

Female sexual function index

Secondary outcome

Female sexual function index subdomain scores

o Desire

o Arousal

o Lubrication

o Orgasm

o Satisfaction

o Pain

Female sexual distress scale

RAND-36 item Health Survey

Center for epidemiologic studies depression scale

Multidimensional fatigue inventory

Maudsley marital questionnaire, marital subscale

EULAR Sjögren's syndrome patients reported index (only in patiënts)

EULAR Sjögren*s syndrome disease activity index (only in patiënts)

Disease duration and use of medication for vaginal dryness and pSS (only in patiënts)

Menopausal status

Study description

Background summary

Sjögren*s syndrome (SS) is a chronic inflammatory and lymphoproliferative disease with autoimmune features. SS is characterised by a progressive lymphocytic infiltration of the exocrine glands, notably the lacrimal and salivary glands. The main clinical features are a progressive dryness of the eyes (keratoconjunctivitis sicca) and dryness of the mouth (xerostomia). Furthermore, various extraglandular manifestations may develop of which restricting fatigue is the most common.
A less known sicca symptom that can occur in SS is vaginal dryness, which can cause dyspareunia. Several studies have shown that the prevalence of vaginal dryness is significantly higher in SS compared to healthy controls. Beluenger et al (2005) found that of all sicca symptoms, vaginal dryness had the highest correlation with a reduction in quality of life. However, the influence of vaginal dryness in primary SS on sexual function and distress has not been studied.
Research regarding the etiology of vaginal dryness has found perivascular inflammation in the vagina as a possible explanation for vaginal sicca symptoms. Treatment of vaginal dryness is limited to symptomatic treatment like the use of vaginal lubricants. Pilocarpine has been proved to be effective in sicca symptoms of the eyes and mouth, but the effect has not been studied for vaginal dryness. This study can provide a basis for further research on the etiology and treatment of vaginal dryness in primary SS.

Study objective

Primary objective: To evaluate the influence of pSS on sexual function, as measured by the female sexual function index (FSFI), in comparison to a healthy control group.
Secundary objective: To evaluate the influence of pSS on subdomains of sexual function, in particular vaginal lubrication. To investigate the relation between vaginal lubrication in pSS and sexual distress and quality of life, taking into account depression, fatigue and marital distress in pSS. To investigate the relation between vaginal sicca symptoms and the disease activity, use of pilocarpine, other medications and menopause.

Study design

Cross-sectional study.

Study burden and risks

The patients from the UMCG pSS cohort and the healthy controls will receive a

patient information leaflet and a form on which they can fill in if they are interested in participation. If they send back this form in the self-adressed envelope they will be send informed consent form and a questionnaire. This self-administered questionnaire will comprise above named subcomponents and will take approximately 30-40 minutes to complete. The participants will be asked to return the questionnaire by mail in a self addressed envelope. In the next routine visit to their regular nurse practitioner or doctor, the EULAR Sjögren*s syndrome disease activity index will be recorded for the patientgroup.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700 RM
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700 RM
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Primary SS according to the revised European - U.S. criteria (in patients).

Female.
Age of 18-60 years.
Written informed consent.

Exclusion criteria

For healthy controls:
The presence of SS or any other autoimmune connective tissue disease such as SLE, reumatoid arthritis, scleroderma or mixed connective tissue disease.

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:	Recruitment stopped
Start date (anticipated):	01-05-2013
Enrollment:	86
Type:	Actual

Ethics review

Approved WMO

Date:	27-03-2013
Application type:	First submission
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	NL43183.042.13

Study results

Date completed:	30-09-2013
Actual enrolment:	89