Sexual function in endometriosis patients

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Primary Objective: To study the effect of different treatment approaches - existing of conservative management, pharmacological treatment and surgical treatment - on sexual function in patients diagnosed with endometriosis. Secondary Objective(s):...

Ethical review	Approved WMO
Status	Pending
Health condition type	Uterine, pelvic and broad ligament disorders
Study type	Observational non invasive

Summary

ID

NL-OMON57217

Source
ToetsingOnline

Brief title
SFIEP

Condition

- Uterine, pelvic and broad ligament disorders

Synonym
endometriosis, Growth of tissue similar to the lining of the uterus outside of the uterus

Research involving
Human

Sponsors and support

Primary sponsor: Haaglanden Medisch Centrum
Source(s) of monetary or material Support: Researchfonds Bronovo

Intervention

Keyword: Endometriosis, Endometriosis Surgery, Endometriosis Treatment, Sexual Function

Outcome measures

Primary outcome

FSFI score before and after treatment of endometriosis, existing of conservative management, pharmacological treatment and/or surgical treatment.

Secondary outcome

Secondary endpoints:

- FSDS score before and after treatment of endometriosis
- EHP-30 score before and after treatment of endometriosis
- Enzian-classification and relation to sexual function, measured by FSFI and FSDS scores
- Enzian-classification and relation to quality of life measured by EHP-30 score

Other study parameters

Age, body mass index (length/weight), race, labour participation, education, medication, smoking, alcohol consumption, drugs, vaping, medical history (obstetric history, details about endometriosis treatment, fertility (treatments), hormonal treatments, psychological treatments, gynaecological surgeries, complications after surgery (if any), contraceptive medication, pelvic physiotherapy treatments, sexological treatments, STD*s), duration of complaints, character of complaints, menstrual cycle, current relationship status and duration, (treatment for) negative sexual experiences, sexual orientation, desire to have children, age of first intercourse.

Study description

Background summary

Around 10% of fertile women suffer from endometriosis with or without adenomyosis (AD), affecting up to 190 million women worldwide.[1] This corresponds to approximately 400,000 women in the Netherlands.
The management of patients with (deep infiltrating) endometriosis and/or adenomyosis includes conservative management, as well as surgical and medical treatments.
Conservative management may consist of psychological support, adequate pain management, pelvic floor physiotherapy and/or dietary interventions, such as the low-FODMAP diet.
Medical options include hormonal treatments such as oral contraceptives, progestogens, GnRH agonists and aromatase inhibitors. Treatment choice depends on the severity of symptoms, patient*s preferences, current wish to have children, potential side effects and/or contra-indications.

Surgical treatment includes laparoscopic resection of endometriosis lesions. In severe DIE, extensive surgery may involve the removal of endometriotic nodules, including procedures such as Low Anterior Resections (LAR) and excision of deep infiltrating endometriosis at the uretero-vesical junction, to diminish dysmenorrhea and complications associated with endometriosis.

Influence of endometriosis on quality of life is well examined and endometriosis has not only physical but also psychological effects, causing depression, anxiety, and compromising social relationships. Furthermore, endometriosis negatively impacts sexual life and social life. Additionally, it leads to a loss of productivity at work and significant utilization of health resources. [2]

Evidence from multiple studies suggests that surgical treatment positively impacts sexual functioning. Recent prospective studies assessing sexual function at multiple time points before and after surgical treatment, show that surgical intervention results in improved FSFI scores. [3, 4]. However, there is still a need for further targeted research on sexual function following endometriosis surgery, with sufficiently large sample sizes. Given that we will conduct this research in an expert clinic, we expect to be able to recruit a substantial sample size.

Less is known about the effect of medical treatment on sexual function. A few studies have investigated this effect, showing improvements in sexual function [5, 6, 7]. Conversely, another study demonstrated a deterioration in sexual functioning following hormonal treatment [8]. Additionally, most studies conducted on this subject have often assessed only a single medication.

The limited evidence and conflicting results, along with focus on only a single medication in most conducted studies, demonstrate the need for additional research into the effects of pharmacological treatment options on sexual functioning.

Conservative treatments, such as dietary interventions, pelvic floor physiotherapy and psychological support, are suggested to positively influence the sexual functioning of patients with endometriosis.[9, 10, 11] However, the evidence regarding the effect of these treatments on sexual functioning remains limited.

Classification of DIE is done by using the Enzian-classification. [12] This classification provides a uniform description and detailed overview of the extent and location of DIE.
The research conducted on the Enzian-classification is currently limited. Research suggests a correlation between the severity grade in Enzian-classification and pain scores. [13] Other research showed an association between dyspareunia and endometriosis lesions in compartment B of the Enzian-classification, corresponding with the uterosacral ligaments. [14]
A study of Bafort et al. investigated pain scores pre- and post-surgery, showing a weak but significance improvements in dyspareunia in patients with the surgical phenotype *rectovaginal endometriosis*.[15] However, this study did not use standardized sexual function questionnaires, and the Enzian-classification was assessed post hoc.
These findings suggest a potential correlation between Enzian-classification and sexual functioning, highlighting the need for further research on the impact of treatment on sexual function, based on Enzian-classification. Understanding the relationship between the Enzian-classification and sexual functioning could contribute to valuable insights for personalized, targeted treatment choices for patients, helping patients gain a clearer perspective on their potential treatment outcomes.

References:
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Study objective

Primary Objective: To study the effect of different treatment approaches - existing of conservative management, pharmacological treatment and surgical treatment - on sexual function in patients diagnosed with endometriosis.

Secondary Objective(s): Enzian Classification and relation to sexual function.

Study design

This will be a prospective cohort study. Patients visiting the endometriosis unit of the HMC
hospital with complaints of endometriosis will be examined during their first visit on the outpatient clinic. There will be determined whether there is endometriosis. Subsequently, treatment will be initiated, consisting of a conservative management approach, pharmacological treatment, or surgical intervention. Patients will receive questionnaires at several moments before and during their treatment.

In case of deep infiltrating endometriosis, the severity of DIE will be classified through the Enzian-classification as usual.[12] The #Enzian classification is based on the known Enzian classification for (DI)E using three compartments (A*vagina, rectovaginal space (RVS); B*uterosacral ligaments (USL) / cardinal ligaments/pelvic sidewall and C*rectum) as well as so-called F (ie far locations) such as the urinary bladder (FB), the ureters (FU), and other extragenital lesions (FO). It additionally covers the involvement of the peritoneum (P), ovary (O), other intestinal locations (sigmoid colon, small bowel; FI), as well as adhesions, involving the tubo-ovarian unit (T) and, optionally, tubal patency.
- Individual compartments or organ involvement are identified with capital letters (P, O, T, A, B, C, F) and arranged in this order.
- The extent of endometriosis is represented by the numbers 1, 2 and 3 in compartments P, O, T, A, B, and C.
- Paired organs (ovary, tube, USL, parametrium, ureter): the severity is arranged separately after the letter (left / right).
- Missing / invisible ovary or tube are described with suffix (m, missing; x, unknown).

At various points during the treatment, questionnaires will be administered regarding the patients' sexual function.

Sexual function will be measured by Female Sexual Function Index (FSFI) and Female Sexual Distress Scale (FSDS). The FSFI is a questionnaire aimed to assess sexual function in women, consisting of 19 questions that include pain, orgasm, sexual desire, arousal, lubrication, pain and satisfaction. [16] The FSDS consists of 12 questions and is developed to measure sexually related personal distress in women. [17] Both questionnaires have been validated and proven reliable, and their psychometric properties are well replicated in a Dutch sample.[18]
General Quality of Life will be measured by Endometriosis Health Profile-30 (EHP-30). This questionnaire measures the health-related quality of life in endometriosis patients.[19] The Dutch EHP-30 has proven to be a useful tool in researching the effect of endometriosis on health status.[20]
Duration of this study is three years. During the follow-up period, data

collection will last for a maximum of 12 months after inclusion. Information regarding treatment will be collected after inclusion. For conservative management, the applied conservative interventions will be recorded, including, for example, dietary interventions, adequate pain management, psychologist consultations, or pelvic floor physiotherapy. For pharmacological management, the specific medication used, including dosage and frequency, will be documented. In case of surgery, the type of surgery will be noted, such as resection of superficial endometriosis, bowel surgery, resection of DIE, treatment of endometrioma, etc. Additionally, when pharmacological or surgical management is applied, any concurrent conservative interventions will also be recorded.
FSFI, FSDS and EHP-30 will be conducted at T0, T1, T2, and T3. T0 represents the first set of questionnaires, which will be sent after signing the informed consent. The second, third, and fourth set of questionnaires will follow, respectively, three (T1), six (T2), and twelve (T3) months after:
- the initial outpatient visit, in the case of conservative management;
- the initiation of pharmacological therapy;
- surgical treatment.
Baseline characteristics will be collected such as age, BMI, education, relationship status, labour participation, medical history, duration of complaints, character of complaints, parity, desire to have children.
Treatment is categorised in conservative management, pharmacological treatment and surgical treatment. The three study groups will be analyzed independently and will not be subject to comparative analysis due to the considerable risk of bias.

The Enzian classification will be determined through transvaginal ultrasound during the initial visit. This classification will be analyzed in relation to sexual function (FSFI and FSDS) and quality of life (EHP-30) at T0, without considering treatment effect.

Data will be collected in the data management system Castor EDC. Data will be collected by the investigators, nurses of the endometriosis department and a research student.

References:
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Study burden and risks

The burden of the study involves filling out the questionnaires, which will take approximately 15 minutes per measuring moment. In total, this amounts to 1 hour of their time. There are no further risks associated with filling out the questionnaires. Another potential burden may arise from the possible discomfort experienced when answering questions related to sexuality.

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 diagnosed with endometriosis through ultrasound, MRI, surgery, or histology
- Patients are 18 years or older

Exclusion criteria

Patients not able to understand Dutch or English
Patients who are not sexually active
Patients with primary vaginismus

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2025
Enrollment:	133
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	06-01-2025
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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	NL86703.058.24