Sampsons Theory of Endometriosis tested in Amsterdam by MRI: a casecontrol study.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Reproductive tract disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON39618

Source ToetsingOnline

Brief title STEAM

Condition

• Reproductive tract disorders NEC

Synonym

appearance of endometrial tissue outside the womb., Endometriosis

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum **Source(s) of monetary or material Support:** Stichting Wetenschappelijk Onderzoek Gynaecologie

Intervention

Keyword: endometriosis, etiology, MRI, transvaginal ultrasound

Outcome measures

Primary outcome

The amount of blood-stained peritoneal fluid measured by TVUS and MRI during menses and during cycleday 20-22 in women with endometriosis versus healthy controls.

Secondary outcome

- the location and the resorption of blood stained peritoneal fluid.

- the changes in volume and aspect of endometrial cysts during the menstrual cycle.

- The molecular- biological relationship between tissue of the endometrial cyste and the endometrium.

- Signal intensity and thickness of the junctional zone in endometriosis patients and controls.

- Apparent diffusion coefficient (ADC) in endometrial cysts, myometrium and junctional zone.

Study description

Background summary

Endometriosis is defined as the presence of endometrial-like tissue (which is in normal circumstances only inside the uterus) within the pelvis and other extra-uterine sites. It is a common estrogen dependent disease which is thought to affect up to 10% of women of reproductive age. This can rise up to 35-50% in women presenting with pelvic pain and infertility or both.

The etiology still remains unclear. Sampson described the theory of retrograde menstruation in 1927. This theory describes the backflow of mentrual fluid from the uterine cavity through the tubes to the peritoneal cavity.

In this study we will test this theory with modern imaging techniques.

Study objective

The main aim is to validate the hypothesis by Sampson on retrograde menstruation by using modern imaging modalities.

•to evaluate if the amount of blood-stained peritoneal fluid measured by TVUS and MRI during menses is greater in women with endometriosis versus healthy controls.

•to evaluate the location and the resorption of blood stained peritoneal fluid by TVUS and MRI.

•to investigate the changes in volume and aspect of endometrial cysts during the menstrual cycle measured by TVUS and MRI.

•to investigate changes in signal intensity and thickness of the junctional zone (JZ) during the menstrual cycle and comparing endometriosis patients and controls by MRI.

•to investigate if diffusion in endometrial cysts, myometrium and junctional zone changes during the cycle and in case of myometrium and the junctional zone between endometriosis patients and controls using diffusion-weighted MRI.

Study design

In an observational, prospective case-control study 20 women diagnosed with endometriosis through laparoscopy presenting with endometrioma are compared with 20 controls without endometriosis.

These women will be examined on cycleday 2-4 and cycleday 20-22 by questionnaires, gynaecological examination, transvaginal ultrasound and a MRI-scan.

When a patient is necessary treated by cystectomie to improve her fertility, a pipelle of the endometrioma will be taken.

Study burden and risks

The risk of this research is very little.

Transvaginal ultrasound is a very safe investigation. MRI is safe to when the patient has no claustrophobic disease or pacemaker.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- at least one patent tube (at HSG or laparoscopy with chromopertubation)
- regular menstrual cycle (28 +/- 3 days)
- cases: presence of endometriosis with uni- or bilateral ovarian endometrioma.
- controls: no presence of endometriosis confirmed by laparoscopy
- signed informed consent form
- negative pregnancy test

Exclusion criteria

- hormone therapy
- contra indications for MRI
- in controls: laparoscopy > 3 years ago
- presence of any malignancy
- frozen pelvis

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:	Recruiting
Start date (anticipated):	16-06-2010
Enrollment:	40
Туре:	Actual

Medical products/devices used

Generic name:	transvaginal ultrasound and MRI
Registration:	Yes - CE intended use

Ethics review

Approved WMO	
Date:	11-02-2010
Application type:	First submission

Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-06-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-11-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-12-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-05-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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 CCMO **ID** NL29485.029.09