Sampsons Theory of Endometriosis tested in Amsterdam by MRI: a case-control study.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26415

Source
NTR

Brief title
STEAM

Health condition

Endometriosis, Retrograde menstruation, theory of Sampson.

Sponsors and support

Primary sponsor: VU University Medical Center, Department of Obstetrics and Gynaecology
Source(s) of monetary or material Support: VU University Medical Center, Department of Obstetrics and Gynaecology

Intervention

Outcome measures

Primary outcome

The difference in the amount of blood-stained peritoneal fluid measured by TVUS and MRI in women with endometriosis versus healthy controls.

Secondary outcome

1. The localisation and amount of resorption of blood stained peritoneal fluid;

2. The volume and aspect of endometrial cysts;

3. Signal intesity and thickness of the junctional zone in endometriosis patients and controls;

4. Apperent 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 dependant 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 remains unclear. Sampson described the theory of menstruation in 1927. This theory describes the backflow of menstrual fluid from the uterine cavity through the tubes to the peritoneal cavity. In this study we will test this theory with modern imaging techniques (TVUS and MRI).

Study objective

To validate the hypothesis by Sampson on retrograde menstruation by using modern imaging modalities.

Study design

N/A

Intervention

On Cycleday 2 and Cycleday 20 a gynaecological investigation, a transvaginal ultrasound and MRI will be performed. Also a bloodsample (serum Ca 125) will be collected.
In case of a cystectomy also a pippelle from the endometrium will be taken.

Contacts

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Eligibility criteria

Inclusion criteria

1. Female<40 years;

2. Subfertility;

3. Patent tubes (at HSG or laparoscopy with chromopertubation);

4. Regular menstrual cycle (28 days +/- 3 days);

5. Cases: presence of endometriosis confirmed by laparoscopy;

6. Controls: no presence of endometriosis confirmed by laparoscopy;

7. Signed informed consent;

8. Negative pregnancy test.

Exclusion criteria

1. Female age>40 years;

2. Hormone therapy;

3. Contra indications for MR imaging (e.g.pacemaker, claustrophobia);

4. Positive pregnancy test;

5. Laparoscopy > 1 year ago;

6. Evidence of tubal occlusion seen at HSG or laparoscopy;

7. Presence of any malignancy;

8. Frozen pelvis.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2010
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-02-2010
Application type:	First submission

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
NTR-new	NL2106
NTR-old	NTR2223
Other	METc VUmc : 2009/329
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A