Diagnostic performance of MRI in the detection of superficial endometriosis:Optimization

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The aim of the study is to optimize the MRI sequences in order to detect superficial endometriosis with high sensitivity and study the preliminary accuracy of an optimized MRI protocol in the detection of superficial lesions related to endometriosis...

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

Summary

ID

NL-OMON31985

Source
ToetsingOnline

Brief title
MRI in superficial endometriosis

Condition

- Uterine, pelvic and broad ligament disorders

Synonym
endometriosis, uterus mucous uncontrolled growth

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: endometriosis, MRI, superficial

Outcome measures

Primary outcome

Primary Objective: to study the preliminary accuracy of an optimized MRI

protocol in the detection of superficial lesions related to endometriosis.

Secondary outcome

na

Study description

Background summary

Surgical excision of endometriosis is an effective treatment for endometriosis-associated subfertility. Surgical intervention improves the rate of spontaneous pregnancy mainly for stage I and II endometriosis.
If women have a regular cycle, a partner with a normal sperm examination, and if they have been unsuccessful in trying to conceive for more than 1 year without moderate to severe cyclic or chronic pelvic pain (requiring at least cyclic or chronic use of pain killers), combined with a normal clinical examination and a normal pelvic ultrasound, most gynecologists are not sure if endometriosis is present and if it is useful to do a diagnostic laparoscopy.
From a clinical perspective, they may have extensive peritoneal endometriosis with or without adhesions associated with subfertility and possibly mild pain.
For this population, a noninvasive diagnostic test would be useful to rule in those with endometriosis, most likely minimal to mild disease, who are known to benefit from surgical therapy for both subfertility and pain. However, none of the known test are sufficcient sensitive in order to miss no women with endometriosis.

Study objective

The aim of the study is to optimize the MRI sequences in order to detect superficial endometriosis with high sensitivity and study the preliminary accuracy of an optimized MRI protocol in the detection of superficial lesions related to endometriosis.

Study design

A female group patients with clinical suspicion of endometriosis MRI will be performed. Only patients who will undergo laparascopy for the diagnosis or therapy of the endometriosis in the clinical set-up will be retrieved.

Study burden and risks

MRI is for as far as known not dangerous. Patients have to stay for around 30-45 minutes in a small bore, and patients who are claustrofobic can object to participate. MRI-scanning is relatively noiseful and for that reason earplugs are given. Since the MRI induces magnetic fields patients with a pacemaker or some metallic parts are refused to participed. Buscopan will be injected intravenously in all patients except for those who have glaucoma or cardiac dysrythmiae.

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

-18-35 years old
-female
-signed informed consent

Exclusion criteria

-contra-indications for laparoscopy
-contra-indications for MRI
-use of agents that suppressing the hormonal state (e.g. GnRH analogues)
-glaucoma

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2008
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	22-04-2008

Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL21879.078.08