Cine-MRI for detection of pouch of Douglas obliteration in endometriosis (pilot study)

Published: 04-04-2018 Last updated: 19-03-2025

To determine whether cine-MRI is able to assess the so-called *sliding viscera* sign in the posterior compartment, an known sonographic indicator for the absence of POD adhesions.

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

Summary

ID

NL-OMON46426

Source ToetsingOnline

Brief title Cine-MRI in endometriosis: pilot study

Condition

• Uterine, pelvic and broad ligament disorders

Synonym 'Endometriosis' 'Endo'

Research involving Human

Sponsors and support

Primary sponsor: Maastricht Universitair Medisch Centrum **Source(s) of monetary or material Support:** Ministerie van OC&W

Intervention

Keyword: Adhesions, Endometriosis, MRI, Pouch of Douglas

Outcome measures

Primary outcome

Detection of sliding viscera sign with cine-MRI.

Secondary outcome

n/a

Study description

Background summary

The decision to perform surgery in patients with deep endometriosis is largely based on the suspected extent of the disease and subsequent risk of complications. This risk increases greatly when adhesions obliterate the pouch of Douglas (POD). Magnetic resonance imaging (MRI) is widely regarded as a reliable diagnostic tool in presurgical assessment of endometriosis, but the static nature of conventional MRI makes it an inferior test for detecting intra-abdominal adhesions. Functional cine-MRI has proven to be a promising imaging technique for the identification of intra-abdominal adhesions in patients with acute or chronic pain.

Study objective

To determine whether cine-MRI is able to assess the so-called *sliding viscera* sign in the posterior compartment, an known sonographic indicator for the absence of POD adhesions.

Study design

A prospective observational pilot study.

If this pilot study shows that cine-MRI is able to assess sliding viscera sign in the posterior compartment, this modality will be added to the conventional MRI protocol in a prospective study comparing the accuracy of MRI and transvaginal ultrasound (TVUS) in predicting the extent of deep infiltrating endometriosis.

Study burden and risks

All participants will undergo a transvaginal ultrasound and MRI. There is no risk involved in participation, other than possible chance findings of unrelated pathology.

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

Aged 18-45 years Endometriosis patients:

- Known POD obliteration, diagnosed either by diagnostic laparoscopy or negative sliding viscera sign on transvaginal ultrasound

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Control subjects: - Positive sliding viscera sign on transvaginal ultrasound

Exclusion criteria

Any contra-indication for MRI (e.g. claustrophobia, non-MRI-compatible implanted devices, metal splinters in eye)

Patient does not want to be informed about potential incidental findings on MRI Endometriosis patients:

- Prior adhesiolysis of POD adhesions.

- History of abdominal surgery (other than diagnostic laparoscopy) as this increases the risk of non-endometriosis adhesions.

- No transvaginal ultrasound performed

Control subjects:

- Known history of endometriosis, pelvic inflammatory disease, intra-abdominal adhesions or abdominal surgery other than diagnostic laparoscopy.

- Signs/symptoms of endometriosis, such as dysmenorrhea, dyspareunia, dyschezia or unexplained subfertility. This is not an exclusion criterion if endometriosis and adhesions have been previously ruled out by diagnostic laparoscopy.

Study design

Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	07-06-2018
Enrollment:	15
Туре:	Actual

Medical products/devices used

Generic name: MRI-scan

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Ethics review Approved WMO

Date:04-04-2018Application type:First submissionReview commission:METC academisch ziekenhuis Maastricht/Universiteit
Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 29313 Source: Nationaal Trial Register Title:

In other registers

Register	ID
ССМО	NL63932.068.17
OMON	NL-OMON29313

Study results

Date completed:	07-12-2018
Actual enrolment:	15