# 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

**Public**
Maastricht Universitair Medisch Centrum

P. Debyelaan 25
Maastricht 6229 HX
NL
**Scientific**
Maastricht Universitair Medisch Centrum

P. Debyelaan 25
Maastricht 6229 HX
NL

# 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

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 |
| Type: | Actual |

### Medical products/devices used

| | |
|---|---|
| Generic name: | MRI-scan |

| | |
|---|---|
| Registration: | Yes - CE intended use |

## Ethics review

| | |
|---|---|
| Approved WMO Date: | 04-04-2018 |
| Application type: | First submission |
| Review 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 |
|---|---|
| CCMO | NL63932.068.17 |
| OMON | NL-OMON29313 |

## Study results

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