Het gebruik van cineMRI voor de detectie van endometriose (pilot studie)

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29313

Source
Nationaal Trial Register

Health condition

Endometriosis, cine MRI, sliding viscera

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht
Source(s) of monetary or material Support: Academisch Ziekenhuis Maastricht

Intervention

Outcome measures

Primary outcome

To determine whether cine-MRI is able to visualize the sliding viscera sign in the posterior compartment in healthy subjects and if the cine-MRI is able to show a reduction in the visceral slide in patients with proven adhesions.

Secondary outcome

Establishing a cine-MRI technique with optimal sequences and non-invasive movements of the patient to adequately induce the visceral slide sign.

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.

The objective of this study is to determine whether cine-MRI is able to assess the so-called ‘sliding viscera’ sign in the posterior compartment, a known sonographic indicator for the absence of POD adhesions.

Women without symptoms or a history of endometriosis will undergo a structured transvaginal ultrasound (TVUS) by a trained sonographer to establish that the sliding viscera sign is positive, i.e. there are no POD adhesions detectable on ultrasound. Participants will then undergo a cine MRI where images are made using different patient instructions. A protocol is developed for the optimal detection of sliding viscera sign with cine-MRI, which is then tested in women with endometriosis and proven POD adhesions.

Study objective

Cine-MRI is able to detect adhesions in the pouch of Douglas in endometriosis patients by visualizing the presence or absence of the sliding viscera sign.

Study design

Evaluation is done by one of the radiologists participating in the study directly following MRI.

Intervention

The use of cineMRI in addition to standard MRI and transvaginal ultrasound for endometriosis in the evaluation of POD visceral slide.

Contacts

Public
MUMC+ department of Radiology

R.R.M. Vogels
P.O. Box 5800

Maastricht 6202 AZ
The Netherlands
0612644007
Scientific
MUMC+ department of Radiology

R.R.M. Vogels
P.O. Box 5800

Maastricht 6202 AZ
The Netherlands
0612644007

Eligibility criteria

Inclusion criteria

- Female aged 18-45 years

- control subjects: positive sliding viscera sign on transvaginal ultrasound.

- Endometriosis patients: known POD obliteration diagnosed either by diagnostic laparoscopy or negative sliding viscera on TVUS.

Exclusion criteria

- Any contra-indication for MRI

- 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-endometrious adhesions

- no transvaginal ultrasound

Control subjects:

- known history of endometriosis, PID, intra-abdominal adhesions or abdominal surgery other than diagnostic laparoscopy

- signs/symptoms of endometriosis, such as dysmenorrhea, dyspareunia, dyschezia or unexplained subfertility

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2018
Enrollment:	15
Type:	Actual

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 46426
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6862
NTR-old	NTR7040
CCMO	NL63932.068.17
OMON	NL-OMON46426

Study results