

# Endometriosis diagnostics-Fusion MRI-ultrasound

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To determine the feasibility of Fusion MRI-ultrasound for the uterus and ovary. To determine if Fusion MRI-ultrasound is more accurate for the diagnosis of endometriosis than MRI or ultrasound alone.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Menstrual cycle and uterine bleeding disorders
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON42075

### Source

ToetsingOnline

### Brief title

Endometriosis diagnostics-Fusion MRI-ultrasound

### Condition

- Menstrual cycle and uterine bleeding disorders

### Synonym

adenomyosis, endometriosis

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Bronovo Ziekenhuis

**Source(s) of monetary or material Support:** Researchfonds Bronovo ziekenhuis

## Intervention

**Keyword:** diagnosis, Endometriosis, MRI, transvaginal ultrasound

## Outcome measures

### Primary outcome

Pilot:

Is calibration feasible in gynecological patients?

Study:

correlation between fusion MRI-ultrasound and conventional MRI and between conventional ultrasound.

### Secondary outcome

none

## Study description

### Background summary

Endometriosis is defined as the presence of endometrial glands and stroma at extra uterine sites. Prevalence is estimated at 5-10% in women of reproductive age and up to 50% in women with infertility. The average time from the first symptoms until the diagnosis of endometriosis is 7-8 years.

Patients with endometriosis and a frozen pelvis and/or nodules in the bowel and/or nodules in the bladder are best managed in a multidisciplinary team. A correct diagnosis of endometriosis is necessary.

Transvaginal ultrasound and Magnetic Resonance Imaging both have advantages and disadvantages. Fusion MRI-ultrasound may be more accurate in the diagnosis of endometriosis and hopefully reduce the time between the first symptoms and diagnosis.

### Study objective

To determine the feasibility of Fusion MRI-ultrasound for the uterus and ovary.  
To determine if Fusion MRI-ultrasound is more accurate for the diagnosis of

endometriosis then MRI or ultrasound alone.

## **Study design**

Pilot:

Inclusion of 10 patients with a MRI for a benign disease. Within 3 weeks of the MRI a transvaginal ultrasound according to the fusion protocol will be performed: first, the MRI and ultrasound will be calibrated. Then, a few anatomical landmarks will be chosen (cervix, urethra, rectum, ovary) and the distance from the landmark to the calibrationpoint will be measured. After 5 minutes, the measurement will be repeated to determine the reproducibility.

Study:

Inclusion of 25 patients with a MRI for endometriosis preoperatively. Within 3 weeks of the MRI scan a transvaginal ultrasound according to the fusion protocol will be performed. Calibration as above. Then, every spot suspected for endometriosis on conventional ultrasound or MRI will be reassessed: endometriosis yes/no.

## **Study burden and risks**

1 extra visit to the outpatient clinic. During that visit a transvaginal ultrasound will be performed.

## **Contacts**

### **Public**

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### **Scientific**

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## **Trial sites**

## Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Pilot 1: patients who need a MRI for a benign illness (no. 10)

Pilot 2: patients who need a MRI for endometriosis (no. 25)

patients age >18 years

### Exclusion criteria

Patients under the age of 18 years

patients with a contraindication for a MRI scan

patients who are unable to have a transvaginal ultrasound

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 15-07-2014

Enrollment: 35

Type:

Actual

## Ethics review

Approved WMO

Date: 04-07-2014

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO

Date: 23-02-2015

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

## 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**

CCMO

**ID**

NL48237.098.14