

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.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Menstrual cycle and uterine bleeding disorders
Study type	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)

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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