

Interobserver differences for the use of elastography for diagnosing intrauterine pathology, with MRI as reference test.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25829

Source

Nationaal Trial Register

Health condition

Elastography, fibroids, adenomyosis

Sponsors and support

Primary sponsor: University medical center

Source(s) of monetary or material Support: Zelfgefinancierde sponsor = verrichter
Samsung Medison

Intervention

Outcome measures

Primary outcome

The degree of agreement for the detection of intrauterine pathology.

Secondary outcome

The degree of agreement of the size, type and color characteristics seen with elastography,

of the abnormality and normal uteri.

Study description

Background summary

N/A

Study objective

Being able to differentiate between fibroids and adenomyosis is important because the therapeutic options differ between the two. MRI is usually used for follow-up when ultrasound results are not conclusive and adenomyosis is suspected. Since uterine bleeding is a common problem and MRI is an expensive tool, a new tool is desirable. Elastography could be a valuable tool in addition to regular 2D ultrasound.

Study design

Patients will receive one MRI and at one timepoint sonography of the uterus.

Intervention

1. 2-D greyscale sonography and the elastography;
2. MRI.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients older than 18 years;
2. Patients with uterine fibroids;
3. Patients with adenomyosis;
4. Patients with a normal uterus (control group).

Exclusion criteria

1. Patient with contraindications for MRI;
2. Patient started hormonal medication started;
3. Postmenopausal woman.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-09-2012
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date: 04-01-2013

Application type: First submission

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	ID
NTR-new	NL3548
NTR-old	NTR3778
Other	VUMC : 12/445
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A