# The use of CEUS in the assessment of uterine fibroids, a feasibility study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms female benign
Study type	Observational invasive

## Summary

#### ID

**NL-OMON40659** 

**Source** ToetsingOnline

Brief title CEUS for fibroids

## Condition

• Reproductive neoplasms female benign

**Synonym** fibroids, myoma

**Research involving** Human

## **Sponsors and support**

**Primary sponsor:** Vrije Universiteit Medisch Centrum **Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

Keyword: CEUS, fibroids, ultrasound, vascularization

#### **Outcome measures**

#### **Primary outcome**

3D power Doppler and contrast enhanced ultrasound will be performed at women with a clinical suspicion of uterine leiomyomas on TVU and these results will be compared with dynamic MRI. The primary outcomes of the current pilot study are testing the feasibility of CEUS in visualizing uterine leiomyomas and their vascularization, assess the accuracy of CEUS in the detection of uterine leiomyomas and the number of leiomyomas detected with CEUS and to observe the enhancement pattern and time-intensity curve obtained from CEUS of which parameters of quantification of vascularization will be calculated.

#### Secondary outcome

Characterization of uterine leiomyomas visualized with contrast enhanced ultrasound, and to describe their vascular pattern by making a micro-vascular imaging.

# **Study description**

#### **Background summary**

With Contrast Enhanced UltraSound (CEUS) the microvascularisation of uterine leiomyomas can be visualized. In general practice we use color Doppler and power Doppler to get an impression of the (macro) vascularity of fibroids and to differentiate fibroids from other uterine abnormalities such as adenomyosis. CEUS is able to present macro vascularity as well but it has additional abilities to study the vascularity in more detail: 1) microvascularity can be studied, 2) dynamic patterns that reflect vessel functionality can be studied and 3) parameters for quantification of vascularization based on time-intensity curves of regions of interest can be calculated (arrival-time, peak-time, wash-in time, mean transit time, peak value, wash-in rate and area under the curve). These parameters could replace (dynamic) MRI for the evaluation of fibroids and its vascularity. We hypothesize that in the future these outcomes could be useful for the prediction of fibroid responsiveness for specific therapies and for the monitoring of therapeutical respons. So in theory it could be advantages for the treatment choice and monitoring of uterine leiomyomas.

In the past years numerous studies have been preformed with CEUS, but only a few small series were reported on using CEUS in the assessment of uterine leiomyomas. However it has not been compared to other sonographic modalities such as 3D power Doppler in a structured way.

The aim of the current study is to compare CEUS outcomes with 3D power Doppler parameters and to use dynamic MRI as a reference test. We will start with a pilot study to test the feasibility of this technique in our hand and with our software. Based on these outcomes a final study will be designed, including a proper power calculation and optimalisation of the settings of the machine and software used to analyze the images.

### Study objective

The objectives of the current pilot study are:

1 to test the feasibility of the used vaginal probe and machine, settings and software that is currently used for the evaluation of prostates for uterine fibroids and to see if we need any modifications of the settings and the analyses.

2 to compare the main outcomes of vascularity with comparable outcomes of dynamic MRI in order to calculate a mean difference and SD for future power calculation.

3 to compare the outcome parameters of dynamic MRI with standard US power doppler outcomes (i.e. 3D mean vascular index of the entire fibroid volume, the mean vascular index of 2D surface of the plane with the largest diameter). 4 to learn and gain experience with the contrast enhanced ultrasound technique, determine the optimal dosage of contrast agent required for optimal visualization of fibroids and to standardize the settings of the machine and software used to analyze the images.

## Study design

A prospective observational pilot study of ten women who are clinically suspected of having uterine leiomyomas who visit the outpatient department of the VUmc or the AMC between March 2014 and June 2014. All patients with the suspicion of uterine fibroids on conventional ultrasound that meet our selection criteria will be asked to participate in the study. After informed consent, a CEUS and a (dynamic) MRI will be performed according to a standardized protocol. 3D US power Doppler sweep is stored of all women that visit our outpatient department with a suspicion of fibroids are stored as a part of our routine.

The contrast enhanced ultrasound will take place in the Academic Medical Centre in Amsterdam, because they have the expertise and the equipment required to make the contrast enhanced ultrasounds. The dynamic MRI will take place in the VU Medical Centre.

The exclusion criteria of the current pilot study include:

- Postmenopausal woman
- Woman with an known allergy to SonoVue or any of its components
- Woman with an history of any clinically unstable cardiac condition including class III/IV cardiac failure or right to left shunts
- Woman who have had a severe cardiac rhythm disorders within the last 7 days
- Woman with severe pulmonary hypertension of uncontrolled systemic
- hypertension or respiratory distress syndrome
- Contra-indications for dynamic MRI

#### Study burden and risks

There is a small anticipated risk for participants. After the use of CEUS in thousands of patients, adverse events appear to be transient, mild and rare. The side effects mostly consist of transient alteration of taste, local pain at the injection site and facial or general flush. In rare cases allergic reaction to the contrast agent is described. Patients will be informed of the risk during intake, and it will be described in the study information. If the results of the study show that contrast enhanced ultrasound can provide

If the results of the study show that contrast enhanced ultrasound can provide a precise depiction of the leiomyomas vascularisation this can be helpful for the characterization, treatment choice and monitoring of fibroid treatment.

# Contacts

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# **Trial sites**

## **Listed location countries**

Netherlands

# **Eligibility criteria**

Age Adults (18-64 years) Elderly (65 years and older)

### **Inclusion criteria**

-Older than 18 years of age -Suspected uterine leiomyomas -Signed informed consent

## **Exclusion criteria**

-Postmenopausal woman

- Woman with an known allergy to SonoVue or any of its components

-Servere hartdissease or recent unset of rhytmic disorders

-Contraindications for MRI

# Study design

## Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

## Recruitment

NL

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Recruitment status:	Recruitment stopped
Start date (anticipated):	26-06-2014
Enrollment:	10
Туре:	Actual

# **Ethics review**

Approved WMO	
Date:	08-05-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

# **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** NL47855.018.14