# Visualizing uterine microvasculature using contrast-enhanced ultrasound for differentiating between uteri with adenomyosis, myoma, sarcoma, and no uterine disorders

Published: 02-01-2024
Last updated: 18-01-2025

Primary objective:1) To determine the discriminating ability of the microvasculature between uteri with adenomyosis, myomas and no uterine disorders. Secondary Objectives: 2) To determine the discriminating ability of the microvasculature between...

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Reproductive neoplasms female benign |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON56469

**Source**
ToetsingOnline

**Brief title**
UteroVue

### Condition

- Reproductive neoplasms female benign

**Synonym**
adenomyosis, growth of inner lining uterus into uterine wall

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Amsterdam UMC
**Source(s) of monetary or material Support:** NWO;domein Toegepaste en Technische Wetenschappen,Samsung

## Intervention

**Keyword:** Contrast-enhanced ultrasound, Gynaecology, Microvasculature, Uterine disorders

## Outcome measures

### Primary outcome

Blood flow parameters (e.g. arrival time, peak intensity, wash-out time)

obtained from time-intensity curves of adenomyosis, myomas and uteri without a

disorder.

### Secondary outcome

- Blood flow parameters of sarcomas

- CEUS enhancement characteristics (e.g. homogeneity, order of enhancement,

echogenicity) of adenomyosis, fibroids, sarcoma and uteri without disorders

- Diagnostic performance (sensitivity, specificity and diagnostic accuracy) of

detecting uterine disorder based on:

o CEUS classification model for adenomyosis

o CEUS classification model for sarcomas

o Conventional ultrasound (assessment of the gynecologist)

o MRI (assessment of the radiologist)

o Histology (assessment of the pathologist)

o Combination of all diagnostic tests used in the patient, including clinical

presentation (assessment of the gynecologist)

# Study description

### Background summary

The smallest blood vessels in our body contain important information. This architecture of this so-called microvasculature, the level of angiogenesis, blood flow patterns, blood flow velocity provide information about the specific tissue or disorder. The microvasculature of benign disorder is, for example, different from malignant disorders. Conventional sonography and Doppler can only image larger blood vessels. Contrast-enhanced ultrasononngraphy, by means of intravenously injected contrast agents, is capable of imaging the microvasculature. In addition, contrast-enhanced images can be fully quantified. The detailed information and quantification support an accurate diagnosis of for instance adenomyosis and sarcoma. Adenomyosis is a benign uterine disorder that is often missed on conventional ultrasonography. Whereas a sarcoma is a rare malignancy that cannot be discrimated from the common benign myoma (fibroid) using current imaging techniques.

### Study objective

Primary objective:
1) To determine the discriminating ability of the microvasculature between uteri with adenomyosis, myomas and no uterine disorders.

Secondary Objectives:
2) To determine the discriminating ability of the microvasculature between uterine sarcoma and myomas.

3) To compare the diagnostic performance between a) CEUS; b) conventional ultrasound; c) MRI; d) histology.

### Study design

A prospective, observational study where contrast-enhanced ultrasonography will be performed on 253 subjects who visit the outpatient Gynaecology clinic at Amsterdam UMC, location AMC, or UZ Leuven, Belgium, between January 1st, 2024 and January 1st, 2029.

### Study burden and risks

There is a small anticipated risk for participants. After the use of SonoVue in tens of thousands of patients, adverse events have shown to consist of

transient alteration of taste, head ache, local pain at the injection site and facial or general flush. These side effects are in general transient, mild and rare. In extreme rare cases an allergic reaction to the contrast agent is described.

# Contacts

**Public**
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105 AZ
NL
**Scientific**
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105 AZ
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

- >18 years of age
- Have a uterus
- Signed Informed Consent

### Exclusion criteria

- Pregnant women
- Known allergy to SonoVue or any of its components
- Severe heart disease or recent onset of cardiac rhythm disorders
- Severe pulmonary hypertension
- Use of angiogenesis inhibitor

## Study design

### Design

| | |
|---|---|
| Study type: | Observational invasive |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Diagnostic |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 12-01-2024 |
| Enrollment: | 223 |
| Type: | Actual |

## Ethics review

| | |
|---|---|
| Approved WMO Date: | 02-01-2024 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 02-09-2024 |
| Application type: | Amendment |

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 | ID |
|---|---|
| CCMO | NL83391.018.23 |