

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

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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

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 ultrasonography, 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 discriminated 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

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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

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