Optimizing machine settings for contrast-enhanced ultrasound imaging of uterine disorders

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Optimize settings for contrast-enhanced ultrasound imaging of uterine disorders to obtain quantifiable images

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

Summary

ID

NL-OMON52905

Source
ToetsingOnline

Brief title
CEUS imaging of uterine disorders

Condition

- Reproductive neoplasms female benign

Synonym
adenomyosis, growth of inner lining uterus into uterine wall

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

Outcome measures

Primary outcome

Quality of the contrast-enhanced images. Images will be marked 'high-quality / sufficient quality / insufficient quality'. The high- and sufficient quality images will be further analysed.

Secondary outcome

- Enhancement pattern and microvascular architecture of uteri (subjective description)

- Full quantification of blood flow parameters from time-intensity curves, such as peak enhancement (maximal level of enhancement, associated with relative blood volume), rise time (time from baseline to peak enhancement, related to blood flow velocity), and wash-in rate (peak enhancement/rise time) using VueBox software (Bracco) and customized software by prof. M. Mischi (TU Eindhoven).

- Power calculation for further research

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 much 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 the larger 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. Whereas a sarcoma is a rare malignancy that cannot be discrimated from the common benign myoma (fibroid) using current imaging techniques.

Study objective

Optimize settings for contrast-enhanced ultrasound imaging of uterine disorders to obtain quantifiable images

Study design

A prospective, observational pilot study to optimize the CEUS settings with 30 women who visit the out-patient gynaecology clinic between February 1rst, 2021 and January 31rst, 2024. An initial conventional sonography exam will be performed in line with standard clinical care. After informed consent women an appointment will be made for the contrast-enhanced ultrasound.

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 appear to consist of transient alteration of taste, headache, 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. Patients will be informed of the risk and it will be described in the study information.

The burden for the participants is low as well. For the current study they undergo one CEUS scan. Though permission will be asked if they may be contacted in the future for a potential following clinical studies.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- 18 years of age or older
- abnormal uterine bleeding complaints
- signed informed consent

Exclusion criteria

- Woman with known allergy to SonoVue or any of its components
- Severe heart disease or recent unset of rhythmic disorders
- Pregant women

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):	30-05-2022
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	19-02-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-01-2023
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	NL71846.029.19