Orthogonal polarization spectral (OPS) imaging of the microcirculation of the endometrium - a feasibility study

Published: 11-05-2016
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Main objective of this study is describing the functional morphology of the microcirculation of the endometrium.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Menstrual cycle and uterine bleeding disorders
Study type	Observational invasive

Summary

ID

NL-OMON43621

Source
ToetsingOnline

Brief title
Microcirculation of the endometrium.

Condition

- Menstrual cycle and uterine bleeding disorders

Synonym
menses; heavy menstrual bleeding

Research involving
Human

Sponsors and support

Primary sponsor: Gynaecologie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: endometrium, microcirculation, morphology

Outcome measures

Primary outcome

Measurement of microcirculatory parameters of the endometrium using orthogonal polarization spectral (OPS).

Secondary outcome

Identifying whether the findings on the microcirculatory architecture and capillary density of the endometrium can be linked to clinical symptoms.

Study description

Background summary

The aetiology of abnormal uterine bleeding is poorly understood. The endometrium is the mucous lining of the cavity of the uterus, which, in response to hormones from the ovaries, builds up during the menstrual cycle and, in absence of conception, is shed. This shedding of the endometrium is what constitutes the menstruation. Little is known about the contribution to abnormal blood loss by the endometrium itself. The vascularisation and microcirculation of the endometrium might play an important role in the causation of abnormal uterine bleeding. In order to be able to study the endometrium as a possible cause of abnormal bleeding, firstly it is necessary to be informed about the feasibility of studying the microcirculation of the endometrium in a reproducible manner. To date, no in vivo study of the functional morphology of the microcirculation of the endometrium has been reported.
The aim of this study is to investigate the use of the orthogonal polarization spectral (OPS) imaging modes for evaluation of the microcirculation of the endometrium.

Study objective

Main objective of this study is describing the functional morphology of the microcirculation of the endometrium.

Study design

Observational pilot study.

Study burden and risks

One burden of this study consists of the consultation in which the patient is informed about and counselled for this study. This will take place in the outpatient clinic, and will approximately add an extra 20 minutes to their clinic visit, when they are being planned to have a hysterectomy, TCRM or diagnostic hysteroscopy. Another burden will be the procedure of the actual investigation of the endometrium using the orthogonal polarization spectral (OPS) imaging device. The risk associated with this investigation is the risk of perforation of the uterine wall. This is a small risk, consistent with the risk of perforation during conventional hysteroscopy, and is estimated to be around 1:1000.
For the study subject, there are no benefits in participating in this study

Contacts

Public
Selecteer

Meibergdreef 9 9
Amsterdam 1105 AZ
NL
Scientific
Selecteer

Meibergdreef 9 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

Patients scheduled for hysterectomy, transcervical fibroid resection or diagnostic hysteroscopy for benign condition.

Exclusion criteria

Presence or suspicion of (pre-)malignant condition of endometrium, uterus and/or cervix.
Stenosis of cervix/cervical canal.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	Microcirculation assessments of the endometrium will be performed using an orthogonal polarization s
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	11-05-2016
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	ID
CCMO	NL53160.018.16