The role of endometrial angiogenesis in patients with bleeding disorders in case of submucous fibroids

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To compare vascular density and angiogenic factors in normal endometrium and endometrium covering submucous fibroids in patients with submucous fibroids.

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

Summary

ID

NL-OMON36239

Source
ToetsingOnline

Brief title
Endometrial Angiogenesis related to fibroids.

Condition

- Reproductive neoplasms female benign
- Menstrual cycle and uterine bleeding disorders

Synonym
Fibroid, leiomyomata

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: Angiogenesis, Fibroids, Imaging, Menstruation

Outcome measures

Primary outcome

Differences in histological vascular density (based on CD34/31) in endometrium covering fibroids versus normal endometrium.

Secondary outcome

Differenes in kwantified VEGF-A, VEGF-B, VEGF-C, FGF, Estradiol receptor, Progesterone receptor expression, kwantified hysteroscopic vascular density (using Narrow Band Imaging). Level of CD34/31 related ki67 expression.
The relation between endometrial vascularity index and angiogenic profile in endometrium covering a fibroid with severity of menstrual bleeding (PBAC) and total number of days will be assessed.
Potential prognostic parameters: age, cycle day, OC or GnRHa use, fibroid size and level of protrusion (GIS) and vascular indices measured with 3D TV-US will be registered.

Study description

Background summary

Submucous fibroids are an important cause of bleeding disorders in women, and account for a substantial part of all consultations of gynaecologists. However, the etiology of bleeding disorders caused by submucous fibroids is unknown. Better understanding of the etiology is essential to develop more effective therapies with fewer side effects. We hypothesize that endometrial angiogenesis plays a key role in these bleeding disorders.

Study objective

To compare vascular density and angiogenic factors in normal endometrium and endometrium covering submucous fibroids in patients with submucous fibroids.

Study design

A prospective cohort study

Study burden and risks

The diagnostical traject and TCRM will be performed according to the standard used protocol. The only difference with respect the standard procedure is that we add color-doppler to our normal performed TV-US and that during TCRM we will collect the samples of removed endometrium and fibroid tissue separately. Additionally we will take one extra sample of normal endometrium. The additional risk of taking the additional endometrium samples is negligible. Patients will be followed up by standard protocol after TCRM.

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

Premenopausal women, aged above18 years, with a regular menstrual cycle planned for a transcervical hysteroscopic resection (TCRM) of submucous fibroids.

Exclusion criteria

Occlusion or embolization of uterine arteries in the history, risk of pelvic inflammatory disease, known endometrioses, cervical cancer or pregnancy.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2012
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	02-08-2011
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	NL34523.029.10