The myoma vascularity study: Sonographic features of fibroids before and during non-surgical therapy and/or expectant management.

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To study the value of sonographic features including vascularity in the prediction of fibroids* volume change at follow-up during their (1) natural course or (2) long-term use of exogenous hormone exposure; after initiation of (3) SPRMs e.g. Esmya…

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

Summary

ID

NL-OMON50341

Source
ToetsingOnline

Brief title
MYOVASC

Condition

- Reproductive neoplasms female benign

Synonym
fibroid, myoma

Research involving
Human

Sponsors and support

Primary sponsor: Gynaecologie

Source(s) of monetary or material Support: Samsung

Intervention

Keyword: fibroid, myoma, sonography, vascularity

Outcome measures

Primary outcome

Volume reduction per study group after:

1. Natural behaviour - 1 year

2. Long-term exogenous hormonal exposure - 1 year

3. SPRMs e.g. Esmya or GnRH-analogues - 3 months

4. Initiation of exogenous hormonal exposure - 1 year

5. Embolization - 6 months

6. Ablation therapy - 6 months

Secondary outcome

All study groups:

1. UFS-Qol

2. EQ-5D score

3. PBAC-score

4. Haemoglobin level

5. Treatment failure rate

6. (Re)intervention rate

Study description

Background summary

20-30% of women of reproductive age have leiomyomas, causing symptoms like dysmenorrhea and pelvic pain which both effect quality of life.[1-4] The natural behaviour of uterine fibroids is to grow between 7 to 84% in 3 to 12 months.[5-7] Non-surgical options to treat uterine fibroids are non-hormonal or hormonal medical therapies and minimally invasive interventional radiologic techniques. Exogenous hormone exposure including COC, POP or Mirena give in conflicting literature minimal growth to 60% volume shrinkage. [8, 9]] Selective progesteron receptor modulator e.g. Esmya and GnRH-analogues intent to reduce fibroids volume after several months; GnRH-agonists provide a 31-63% shrinkage and less frequently applied GnRH-antagonists 14.3 - 42.7%.[10-16] Esmya gives a volume reduction varying between 10 to 48%.[17] Radiological technique like embolization decreases dominant fibroid volume with 40-70%.[1, 18-22] UAE fails in case of devascularized or minimal vascularized fibroids.[23] Ablation techniques show shrinkage up to a maximum of 90% depending e.g. which treatment.[24-41] Clear prognostic models to predict the effect on fibroid related symptoms and volume reduction are lacking. We postulate higher vascularity to be related to 1) larger fibroid growth during the natural course or during exogenous hormonal exposure; 2) more effective shrinkage during progestogens, GnRH-analogues, SPRMs e.g. Esmya and UAE; but 3) less effective after ablation therapy.

References see Attachment C1.

Study objective

To study the value of sonographic features including vascularity in the prediction of fibroids* volume change at follow-up during their (1) natural course or (2) long-term use of exogenous hormone exposure; after initiation of (3) SPRMs e.g. Esmya or GnRH-analogues treatment or (4) exogenous hormonal exposure; or after (5) embolization or (6) ablation therapy.

Study design

Observational cohort study during 5 years in the outpatient clinic.

Study burden and risks

There are no risks associated with this research as the intervention concerns questionnaires, blood tests and vaginal ultrasound. These measurements are also applied in daily practice, the burden for the patient is time. Extra in the contect of the study is a couple of times a questionnaires which last a maximum of 5-15 minutes. Some of the questionnaires are standard care. The treatment considering the fibroid(s) is independent of this research.

Contacts

Public
Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- <=3 fibroids (except for embolization or ablation: multiple fibroids are allowed, if >= 1 fibroid is accessible for transvaginal ultrasound)
- Maximal diameter >=1.5 cm and <= 10 cm
- Diagnosed on ultrasound examination
- Informed consent
- No or non-surgical treatment

Exclusion criteria

- Any fibroid treatment in the last 3 months in case of (3) SPRM e.g. Esmya or GnRH-analogues (except for exogenous hormone exposure) or (1) no treatment - Age < 18 years - Fibroids not accessible for transvaginal ultrasonography -

Suspicion for malignancy - Postmenopause - Severe adenomyosis - Pregnancy - Contra-indication for the planned treatment - Use of aromatase inhibitors or tamoxifen - Infertility treatment with use of clomifene and/or follicle-stimulating hormone - Breastfeeding

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-09-2018
Enrollment:	580
Type:	Actual

Ethics review

Approved WMO Date:	20-09-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-10-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-02-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	17-01-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-03-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-03-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-11-2024
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	NL63389.029.17