

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

Published: 20-09-2018

Last updated: 21-12-2024

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...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Reproductive neoplasms female benign
<b>Study type</b>	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-QoI
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 context 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

De Boelelaan 1117  
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NL

### Scientific

Selecteer

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

### Inclusion criteria

- $\leq 3$  fibroids (except for embolization or ablation: multiple fibroids are allowed, if  $\geq 1$  fibroid is accessible for transvaginal ultrasound)
- Maximal diameter  $\geq 1.5$  cm and  $\leq 10$  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