In depth analysis of biological tissue characteristics of uterine fibroids using new MRI techniques

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Uterine, pelvic and broad ligament disorders
Study type	Observational invasive

Summary

ID

NL-OMON42789

Source
ToetsingOnline

Brief title
MaSS

Condition

- Uterine, pelvic and broad ligament disorders

Synonym
leiomyoma, uterine fibroid

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Isala Zwolle;afdeling Radiologie

Intervention

Keyword: Leiomyoma, Magnetic Resonance Imaging (MRI), Stratification and quantification, Tissue characteristics

Outcome measures

Primary outcome

The main exploratory study parameter is the distribution and variation of MRI

parameters (ADC map, Ktrans map, ve, vp and T2 map), and the correlation

between the MRI parameters and the Funaki score and clinical UFS-QoL score.

Secondary outcome

Correlation between UFS-QoL improvement after 3 months and the MRI parameters

(ADC map, Ktrans map, ve, vp and T2 map) in medically treated patients

Study description

Background summary

Recent clinical inside shows that uterine fibroid tissue can be very heterogeneous. To refine the stratification of uterine fibroids, more biological information is needed on tissue level. Therefore, in this study we want to analyze a completely new MRI protocol for the characterization of uterine fibroid tissue using multiparametric MRI techniques. The biological characterization of uterine fibroid tissue is useful knowledge in de choice and suitability of treatment options.

Study objective

The primary objective is to determine new biological properties of uterine fibroid tissue using advanced MRI image sequences and to correlate these properties with the currently used simple Funaki classification and with clinical symptoms.

The secondary objective is to determine the correlation of symptom reduction after 3 months of medically treated patients with the in this study evaluated new, extra MRI parameters.

Study design

The proposed research will concern a single-center, experimental explorative research, performed on the departments of gynecology and radiology.

Study burden and risks

Patients included in this study will undergo an MRI examination before proceeding to treatment. During this MRI, use is made of a gadolinium-based MRI contrast agent (Dotarem). This macro-cyclic coated , intra-venous contrast agent is routinely used in current practice and adverse effects are scarce. Besides, patients are asked to complete the UFS-QoL questionnaire.
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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

Patients with a diagnosed uterine fibroid (based on anamnesis, physical examination and vaginal ultrasonography) and uterine fibroid related symptoms are included in the study.

Exclusion criteria

- Post-menopausal patients
- Pregnant patients
- Calcified uterine fibroids
- Severe abdominal obesity
- Uterine artery embolization in medical history
- MRI contra-indications

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):	01-08-2015
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	15-06-2015
Application type:	First submission

Review commission: METC Isala Klinieken (Zwolle)

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	NL53499.075.15