MRI based prognostic biomarkers for treatment success of Minimal invasive treatment for Uterine Fibroids with Magnetic Resonance guided High Intensity Focused Ultrasound (MR-HIFU)

Published: 01-11-2016
Last updated: 17-04-2024

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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-OMON46077

Source
ToetsingOnline

Brief title
MASS II

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 ,Philips

Intervention

Keyword: Imaging predictors, Leiomyoma, Magnetic Resonance guided High Intensity Focused ultrasound (MR-HIFU), Minimal Invasive treatment

Outcome measures

Primary outcome

The main study endpoint is the predictive value of 3 MRI determinants for a

clinical successful treatment.

Secondary outcome

- To correlate these MRI parameters with histopathology.

- The correlation between the non-perfused-volume (treated tissue volume)

measured without the use of a contrast agent (with new MRI sequences) versus

the gold standard (measurements after administration of a contrast agent).

- Measuring the differences between tissue stiffness of the uterine fibroid

before and after MR-HIFU treatment. To correlate these findings with the MR

Imaging to predict treatment outcome and thereby maybe replace the follow-up

MRI in the future.

- Treatment outcomes such as treatment time, thermal dose, number of

sonications, NPV-ratio, adverse events.

Study description

Background summary

Research to the optimal criteria for patient selection for treatment of uterine fibroids with MR-HIFU is worldwide still in progress. In addition to patient selection, clinical and technical tactics are being investigated to increase treatment success. Currently, time is often the limiting factor during MR-HIFU treatment. Therefore, research should focus on making MR-HIFU more time efficient and how to improve treatment outcomes. The results of MR-HIFU treatment still show a large variety in volume- and symptom-reduction. Knowledge of MRI based predictors of success prior to treatment may contribute to an optimization of patient selection, treatment planning and treatment outcomes. Secondly, directly after treatment contrast enhanced MRI is needed for visualizing treatment results. Because HIFU sonications are not allowed after the administration of a contrast agent, treatment results can only be visualized after the total treatment. Therefore, MRI parameters (without the use of a contrast agent) are also studied for capabilities of visualizing treatment results. Recently published literature suggests that ultrasound elastography could also predict treatment outcome. Elastography shows a difference in tissue stiffness of uterine fibroid before treatment, directly after MR-HIFU and during patients* follow-up. Further research should confirm these findings.

Study objective

The aim of this study is to optimize patient selection, to improve treatment efficacy and to better visualize treatment outcome. The objectives of this study will be investigated using the same patient population. For the main endpoints we identified the following MRI parameters: ADC values, quantitative T2 value and ktrans values, in a prior study (MaSS1). These MRI parameters possibly could be a useful tool for patient selection prior to treatment because of their predictive value of treatment outcomes. To improve treatment efficacy, we want to assess if drug administration of carbetocin during MR-HIFU therapy. By modifying the treatment protocol, we try to shorten treatment time and enlarge the ablation volumes. A different purpose of this study is to find a parameter capable of visualizing and measuring the treated tissue as a replacement of contrast-enhanced imaging in order to eliminate the use of a contrast agent. Therefore, we will study the same MRI parameters as mentioned above and additionally we will introduce a new imaging modality: ultrasound elastography. This could become a valuable and inexpensive instrument to evaluate treatment outcome by measuring tissue stiffness. Secondly, it could make clinical follow-up easier, faster and more cost-effective than an MRI.

Study design

The proposed research will concern a single-center study, performed in the departments of Gynecology and Radiology of the Isala hospital. Patients undergoing MR-HIFU treatment within this proposed study will be subdivided into two equal groups. Carbetocin will be administered during the first consecutive

25 treatments (group 1). The control group, last 25 treatments, will receive no additional medication during MR-HIFU treatment compared to standard care. Furthermore, all patients will undergo three extra MRI sequences three times and four times a prolonged ultrasound to perform the elastography measurements. Additionally, they will be asked to complete UFS-QoL questionnaire four times as well as a patient satisfaction survey.

Study burden and risks

Patients included in this study will undergo three extra MRI sequences during MRI examination. Compared to standard care, this will make the duration of the MRI twenty minutes longer. The MRI sequences are acquired in a supine position, just as the conventional sequences during MR-HIFU treatment.
Since patients already receive intravenous medication for pain relief and conscious sedation, no additional interventions are necessary to administer carbetocin during MR-HIFU treatment.
At four time points, when patients have their visit at the gynecologists office (standard care) or when they are hospitalized at the gynecology department (day of the treatment), patients will undergo one extra measurement during the vaginal ultrasound at those visits, the elastography. Compared to standard care, using this elastography function will make the vaginal ultrasound one minute longer each time. Patients will be already at the hospital at those time point, so there is no extra visit necessary.
Also the patients are asked to fulfill the UFS-QoL questionnaire four times. To minimize the burden, patients receive this questionnaire automatically and based on patients* preference they may reply online or return the form during their hospital visits.
The additional MRI sequences and prolonged ultrasounds have no additional risks compared to the standard MRI protocol or standard ultrasound. No additional contrast agent is used compared too standard MR-HIFU protocol. Since carbetocin is widely used during other interventions we expect no adverse events during the administration of this drug and if they do occur, they will be reported to METC and / or CCMO according to the rules.

Contacts

Public
Isala Klinieken

Dr. Van Heesweg 2
Zwolle 8025AB
NL
Scientific
Isala Klinieken

Dr. Van Heesweg 2
Zwolle 8025AB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients diagnosed with a symptomatic uterine fibroid (based on anamnesis, physical examination and vaginal ultrasonography), eligible for MR-HIFU treatment.

Exclusion criteria

- Post menopausal patients
- Pregnant patients
- Calcified fibroids
- Severe abdominal obesity
- MRI contra indications
- Funaki type 3 uterine fibroid
- Uterine fibroid close to sciatic nerve of sacrum, interpostion of bowel or ovary.
- Uterine fibroid diameter < 1 cm or > 10 cm
- Distance skin - uterine fibroid > 10 cm

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):	17-11-2016
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO Date:	01-11-2016
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	22-01-2018
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	29-10-2019
Application type:	Amendment
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	NL56182.075.16