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Myoma Screening Study: use of MRI to predict the outcome of ultrasound treatment for benign tumours of the uterus

Submission date
05/01/2021

Recruitment status
No longer recruiting

Registration date
12/01/2021

Overall study status
Completed

Last Edited
10/08/2022

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Uterine fibroids are noncancerous growths of the uterus that often appear during childbearing years. MR-HIFU uses non-invasive high-intensity focused ultrasound (HIFU) guided by magnetic resonance (MR) to treat uterine fibroids. Research is still in progress on the optimal criteria for patient selection for the treatment of uterine fibroids with MR-HIFU. The results of MR-HIFU treatment show a large variety in volume and symptom reduction. Knowledge of MRI-based predictors of success before treatment may improve patient selection, treatment planning and treatment outcomes. Secondly, directly after treatment contrast-enhanced MRI is needed to see the treatment results. Because HIFU sonications are not allowed after the use of a contrast agent, treatment results can only be seen after the total treatment. Therefore, MRI parameters (without the use of a contrast agent) are also studied for visualizing treatment results. The aim of this study is twofold. The first aim is to study the MRI parameters for predicting treatment outcomes before treatment. The second aim is to find an MRI parameter capable of visualizing and measuring the treated tissue as a replacement for contrast-enhanced imaging in order to eliminate the use of a contrast agent.

Who can participate?
Women, aged between 18 and 59, diagnosed with uterine fibroids and related symptoms and willing to undergo MR-HIFU treatment

What does the study involve?
An MRI scan with three additional MRI sequences will be performed to decide eligibility. If eligible and willing to undergo MR-HIFU treatment, a symptom-specific and quality of life questionnaire needs to be filled in. A comparable MRI scan will be performed 6 months after MR-HIFU treatment and the same questionnaire needs to be filled in at 3, 6 and 12 months after treatment.

What are the possible benefits and risks of participating?
Patients included in this study will undergo three extra MRI sequences during MRI examination. The additional MRI sequences have no additional risks compared to standard MRI. No additional

contrast agent is used compared to standard MR-HIFU. By participating, patients have the opportunity to undergo the non-reimbursed MR-HIFU treatment and contribute to improving this non-invasive treatment option.

Where is the study run from?
Isala Hospital (Netherlands)

When is the study starting and how long is it expected to run for?
January 2015 to April 2020

Who is funding the study?
Isala Hospital (Netherlands)

Who is the main contact?
Dr M.F. Boomsma
m.f.boomsma@isala.nl

Contact information

Type(s)
Scientific

Contact name
Dr Martijn Boomsma

ORCID ID
https://orcid.org/0000-0002-7878-0970

Contact details
Dokter ven Heesweg 2
Zwolle
Netherlands
8025 AB
+31 (0)38 424 5000
m.f.boomsma@isala.nl

Type(s)
Public

Contact name
Ms Kimberley Anneveldt

ORCID ID
https://orcid.org/0000-0002-4546-1148

Contact details
Dokter ven Heesweg 2
Zwolle
Netherlands

8025 AB
+31 (0)38 424 5000
k.j.anneveldt@isala.nl

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
MaSSII: NL56182.075.16, MaSS: NL53499.075.15

Study information

Scientific Title
MaSSII: MRI-based prognostic biomarkers for treatment success of minimal invasive treatment for uterine fibroids with magnetic resonance guided high intensity focused ultrasound (MR-HIFU)
MaSS: In-depth analysis of biological tissue characteristics of uterine fibroids using new MRI techniques

Acronym
MaSSII and MaSS

Study objectives
Multiparametric MRI can be used as a predictive value for a successful MR-HIFU treatment of uterine fibroids. MRI parameters include ADC value (acquired with MR-DWI), quantitative T2-value (acquired with T2-mapping) and K-trans (acquired with DCE imaging). A successful treatment is determined as a symptom reduction of minimal 10 points on the UFS-QoL questionnaire.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MaSSII (NL56182.075.16): Approved 01/11/2016, Isala Zwolle The Netherlands Medical Ethical Review Board (METC Isala
Gebouw Mondriaan, kamer 0.47, Postbus 10400, 8000 GK Zwolle, The Netherlands; +31 (0)38 4243082; METC@isala.nl), ref: 16.0479.
MaSS (NL53499.075.15): Approved 15/06/2015, Isala Zwolle The Netherlands Medical Ethical Review Board (METC Isala
Gebouw Mondriaan, kamer 0.47, Postbus 10400, 8000 GK Zwolle, The Netherlands; +31 (0)38 4243082; METC@isala.nl), ref: 15.0580

Study design
Prospective single-center non-randomized interventional study

Primary study design

Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Uterus myomatosus

Interventions
1. Magnetic Resonance Image-guided High-Intensity Focused Ultrasound (MR-HIFU)
2. Multi-parametric MRI sequences

Patients included in this study will undergo three extra MRI sequences during MRI examination. The MRI sequences are acquired in a supine position, just as the conventional sequences during MR-HIFU treatment. Also, the patients are asked to complete the UFS-QoL questionnaire four times: before MR-HIFU treatment and at 3, 6 and 12 months follow-up.

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
An MRI scan including possible predictive values for a successful MR-HIFU treatment on symptomatic uterine fibroids will be performed before MR-HIFU treatment, directly after MR-HIFU treatment and at 6 months follow-up. The MRI protocol includes the following parameters:
1. ADC value, acquired with MR-DWI
2. Quantitative T2 value, acquired with T2 mapping
3. Ktrans, acquired with DCE imaging

4. Successful treatment defined as a symptom reduction of minimal 10 points on the UFS-QoL questionnaire before MR-HIFU treatment and at 3, 6 and 12 months follow-up

Key secondary outcome(s))
The feasibility of measuring thermal ablation effects from MR-HIFU in the treatment of uterine fibroids, using ADC mapping and T2 mapping MRI sequences at baseline, on treatment day and at 6 months follow-up

Completion date
20/04/2020

Eligibility

Key inclusion criteria
For MRI screening inclusion, the following criteria are applied based on anamnesis, physical examination and vaginal ultrasonography:
1. 18–59 years old
2. Uterine fibroid related symptoms
3. Pre- or perimenopausal

To determine whether the patient is eligible for the MR-HIFU treatment after the screening MRI, the following inclusion criteria are used:
1. Type 1 & 2 uterine fibroids (based on Funaki classification)
2. Diameter of 1-10 cm of dominant fibroid

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
70

Key exclusion criteria
Exclusion criteria for the MRI screening, based on anamnesis, physical examination and vaginal ultrasonography, are defined as follows:
1. Post-menopausal
2. Wish for future fertility
3. Pregnancy
4. Severe abdominal obesity or BMI >40
5. Uterine artery embolization in medical history
6. MRI contra-indications
7. Calcifications in uterine fibroid

To determine whether the patient is eligible for the MR-HIFU treatment after screening MRI, the following exclusion criteria are used.
1. Type 3 uterine fibroids (based on Funaki classification)
2. Calcified or pedunculated uterine fibroids
3. Close to sciatic nerve or sacrum
4. Interposition of bowel or ovary
5. Diameter of <1 cm or >10 cm
6. Distance skin – uterine fibroid >12 cm

Date of first enrolment
15/06/2015

Date of final enrolment
01/02/2019

Locations

Countries of recruitment
Netherlands

Study participating centre
Isala Hospital
Dokter ven Heesweg 2
Zwolle
Netherlands
8025 AB

Sponsor information

Organisation
Isala

ROR
https://ror.org/046a2wj10

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Isala Hospital

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available. Since no approval was requested from the participants to share data, only group-level data on specific outcomes or timepoints can be requested. Complete data registers, statistical analyses etc. cannot be provided.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	MaSS results	01/10/2020	05/01/2021	Yes	No
Results article	MaSSII results	01/07/2020	05/01/2021	Yes	No
Results article		18/12/2021	10/08/2022	Yes	No
Other publications	Lessons learned during implementation	18/12/2021	20/12/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes