Targeted vessel ablation of type 3 uterine fibroids with magnetic resonance guided high intensity focused ultrasound

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To investigate whether it is possible to manipulate perfusion in type 3 fibroids with MR-HIFU.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms female benign
Study type	Interventional

Summary

ID

NL-OMON43988

Source
ToetsingOnline

Brief title
HIFU-TVA of type 3 fibroids

Condition

- Reproductive neoplasms female benign
- Menstrual cycle and uterine bleeding disorders
- Obstetric and gynaecological therapeutic procedures

Synonym
uterine fibroid, uterine myoma

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,Focused Ultrasound Foundation (FUSF)

Intervention

Keyword: MR guided focused ultrasound, Non-invasive therapy, Targeted vessel thermal ablation, Uterine fibroids

Outcome measures

Primary outcome

The main endpoint of this feasibility study is the manipulation of perfusion in the type 3 uterine fibroid. This will be assessed by comparing the results of dynamic contrast-enhanced MRI (DCE-MRI) before and after treatment and after three months (± 2 weeks), i.e. the time to peak values and the regional blood volumes (area under the curve) and of a so-called time-spatial labeling inversion pulse (TimeSLIP) MR sequence that visualizes the blood vessels without usage of a contrast agent before and directly after ablating the feeding vessels (hence, before ablation the remaining fibroid volume). Furthermore adverse effects will be documented up to three months (± 2 weeks) post HIFU.

Secondary outcome

The secondary objective is to assess if the Funaki classification for fibroids is based on differences in perfusion. The relationship between perfusion and the Funaki classification will be investigated using the area under the curve of the dynamic contrast-enhanced series obtained during the clinically obtained screening MR scan.

The tertiary objective is to investigate the effect of the targeted vessel ablation technique on the non-perfused volume (NPV) obtained from contrast

enhanced MR images directly post treatment. Therefore, we will compare the results from this study against the results of previously treated patients. Furthermore, the obtained NPVs will be compared to those reported in literature for type 3 fibroids.

Study description

Background summary

Uterine fibroids or leiomyomas are common benign tumors that arise from smooth muscle cells of the uterus with a prevalence ranging from 20% to 40% in reproductive aged women. Invasive treatments, such as hysterectomy and myomectomy, represent the golden standard with respect to therapy. Alternatively, uterine artery embolization is offered as a less invasive option. However, to date the only non-invasive technique is high intensity focused ultrasound (HIFU) ablation. HIFU ablation uses focused ultrasound waves to non-invasively heat and thermally ablate tissue. Combined with magnetic resonance guidance (MR-HIFU) this allows an entirely non-invasive intervention with anatomical 3D images for the planning of the treatment volume, and real-time temperature monitoring for therapeutic guidance.
A limitation of MR-HIFU is that currently not all types of uterine fibroids are treatable. With respect to MR-HIFU treatment, uterine fibroids are classified in three classes based on the signal intensity of T2-weighted MR images. While MR-HIFU has been shown to result in a reliable positive therapeutic outcome in type 1 and type 2 fibroids, the therapeutic success in type 3 fibroids has so far been limited. The current clinical consensus is that the high perfusion in type 3 fibroids, which causes the heat deposited by the HIFU to be rapidly evacuated from the treatment site, results in insufficient temperatures to induce necrosis in the fibroids. Therefore, a new treatment strategy is proposed to effectively treat type 3 fibroids with MR-HIFU.

Study objective

To investigate whether it is possible to manipulate perfusion in type 3 fibroids with MR-HIFU.

Study design

Single-center, single arm, non-randomized trial. Ten patients will be treated.

Intervention

During the MR-HIFU treatment, the local vascular feeding network will be selectively targeted first with high power sonications with the intention to reduce or interrupt the perfusion of the entire fibroid volume. Subsequently, the remaining fibroid volume will be ablated, similar to the treatment approach of type 1/2 fibroids.

Study burden and risks

The fibroid type and the eligibility for MR-HIFU treatment will be determined on a clinically obtained magnetic resonance imaging (MRI) scan. The result of the scan and information about this study are provided to the patient during a phone call. If the patient is interested, the study information is sent by mail. The patient receives a second phone call to ask if she wishes to participate. If so, an appointment at the hospital is arranged to give details on the study, answer questions, and show the clinical MR scan. If the patient wants to participate, informed consent (IC) is signed. The HIFU treatment will be scheduled in consultation with the patient.
Patients will be sedated during the HIFU intervention, as it is also the case during the standard HIFU treatment of type 1/2 fibroids. Compared to the standard HIFU treatment, the initial selective ablation of the vascular feeding network with high power sonications will be added. The subsequent therapy for the remainder of the fibroid will follow the standard therapeutic HIFU treatment of type 1/2 fibroids.
One week (± 2 days) after the treatment the patient will receive a phone call to ask about adverse events. Three months (± 2 weeks) after the treatment a follow-up MR scan, including a DCE scan, will be performed. In addition, the patient will be asked about any adverse events that might have occurred during a phone call.
Potential adverse effects include skin burns due to heating of the cutaneous and sub-cutaneous abdominal fat and risk of abdominal pain due to the occlusion of the vascular network. To mitigate the risk of skin burns, a cooling cushion is integrated in the HIFU table top and will protect the skin and part of the abdominal fat from overheating.
If women with a type 3 fibroid do not want to participate in this study, they are not eligible for MR-HIFU treatment and are referred by their gynecologist to a more invasive treatment option like uterine artery embolization or hysterectomy.

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

- Women, aged at least 18 years;
- Able to give informed consent;
- A type 3 uterine fibroid;
- Sufficient physical condition to undergo deep sedation;
- Waist circumference that allows positioning on the HIFU table top inside the MR bore.

Exclusion criteria

- Contra-indication for MRI scanning according to the hospital guidelines;
- Contra-indication to injection of gadolinium-based contrast agent, including known prior allergic reaction to any contrast agent, and renal failure (GFR < 30 mL/min/1.73 m2);
- Surgical clips or considerable scar tissue in the HIFU beam path;
- A total of more than ten fibroids;
- Post- or peri-menopausal status;
- Fibroid size >10 cm in diameter;
- Patient has an active pelvic infection;
- Patient has an undiagnosed pelvic mass outside the uterus;

- Patient who is not able to tolerate the required stationary prone position during treatment.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-02-2016
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	MR guided high intensity focused ultrasound (MR-HIFU)
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	06-11-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	05-07-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
ClinicalTrials.gov	NCT02633254
CCMO	NL54736.041.15