Therapeutic MRI-guided High Intensity Focused Ultrasound ablation of uterine fibroids

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

Summary

ID

NL-OMON33136

Source
ToetsingOnline

Brief title
MRI-guided HIFU ablation of uterine fibroids

Condition

- Uterine, pelvic and broad ligament disorders

Synonym
uterine fibroids, uterine leiomyoma

Research involving
Human

Sponsors and support

Primary sponsor: Philips
Source(s) of monetary or material Support: Ministerie van OC&W,Philips Medical Systems

Intervention

Keyword: focused ultrasound, leiomyoma, magnetic resonance imaging, non-invasive therapy

Outcome measures

Primary outcome

1) MR-HIFU treatment volume measurements (effectiveness)

2) HIFU minor complications and adverse events (safety)

3) Absence of unintended thermal lesions (safety)

Secondary outcome

1) Pain and discomfort scores (effectiveness)

2) Return to activity (effectiveness)

3) Length of hospital stay (effectiveness)

4) Quality of life and symptom scores (effectiveness)

Study description

Background summary

Uterine leiomyomas are the most common benign tumor in pre-menopausal women. Symptomatic fibroids impact health and well-being of the female including lost work hours and reduced quality of life. Fibroids occur in 20-50% of women over 30 years of age.
When medical treatment fails, surgical treatment is an option. However, this has a substantial risk of complications and has a long recovery. Minimal invasive treatments have the advantage of a quick recovery and the risk of complications is low.

High Intensity Focused Ultrasound is a completely non invasive treatment for fibroids, recently cleared by the FDA. MRI guided High Intensity Focused Ultrasound (MRgHIFU) used ultrasoundwaves to locally ablate fibroid tissue. Results in relieving symptoms are promising. Treatment is well tolerated well and the recovery period is short.

Study objective

In this study we want to evaluate the safety, technical efficiency, and volume treatment capabilities of the Philips MR guided HIFU system in the treatment of patients with symptomatic uterine fibroids. This information is required for CE labelling of the Philips MR-HIFU system. The importance of this study is that it offers a non-invasive, uterus sparing procedure for the treatment of uterine fibroids in pre- and perimenopausal women.

Study design

A prospective, multi-center, single arm, non-randomized study.

Intervention

In MRI-guided High Intensity Focused Ultrasound (MRgHIFU), the ultrasound generated by the transducer is focused into a small focal tissue volume at specific target locations. During treatment, the beam of ultrasound energy penetrates through soft tissue and causes localized high temperatues (50-70 degrees) for a few sexonds within the target. This produces well defined regions of protein denaturation, irreversible cell damage, and coagulative necrosis within the focal region. Multiple ultrasound exposures are necessary to ablate the targeted tissue. Tight focusing is designed to limit the abaltion the the targeted location.

Applying HIFU energy to a fibroid requires treatment planning, targeting of the ultrasound beam to desired locations and monitoring of the energy delivery. MR imaging provides anatomical details and helps with procedure planning and treatment targeting, including 3D planning and means of measuring the temperature increase generated by HIFU. In addition, MRI provides non-invasive metrics for quantifying the energy/dose delivered to the treatment zone in real-time. Based on these validated MR-HIFU principles, Philips adds volumetric heating with automated feedback approach to provide real-time tissue temperature mapping in multiple planes, steering of the focal point via real-time feedback, and control of the temperature delivering an optimal thermal dose to the target location.

Study burden and risks

Preparation phase:
-questionnaires symptoms and quality of life
-MRI with contrast in prone position
-blood tests and pregnancy test

Treatment day:
-insertion peripheral infusion line and urinary catheter

-administration conscious sedation during treatment
-MRgHIFU treatment (takes about 3 hours, patient lies in prone position in MRI bore)
-post-treatment MRI with contrast
-recovery of sedation (approximately 2 hours), then discharge

After treatment:
-patient diary about discomfort, pain, and pain medication
-1 months after treatment questionnaire about symptoms and quality of life
-MRI with contrast after 1 months

Risks of MRgHIFU:
-Potential complications after the HIFU procedure are nausea, pain, abdominal tenderness, and leg and buttock pain.
-Less potential complications are swelling, urinary difficulty (urinary tract infection), abdominal cramping and internal tissue thermal injury.
-Very rarely seen complications are first degree skin burns, sciatic nerve damage, pain not reacting to drugs, vomiting, above baseline vaginal bleeding, injury to abdominal and pelvic organs (bladder, uterus, intestine) adverse drug reactions (gadolinium), urinary tract infection, fever due to infection, other infection. These complications are very rare.
-Unlikely complications are 2nd and 3rd degree skin burns.

Risks of gadolinium based contrast:
-non serious adverse events: head ache and paresthesia
-1-10%: nausea, vomiting, skin reaction (erythema/itch)
-rare: anaphylactic shock, nefrogenic systemic fibrosis (NSF)

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, age between 18 and 59 years
-Weight < 140kg
-Pre- or peri-menopausal (FSH < 40 mIU/ml)
-Uterine size < 24 weeks gestation
-Transformed SSS score > 40
-Cervical cell assessment by PAP: Normal, Low Grade SIL, Low risk HPV or ASCUS (Atypical Squamous Cells of Uncertain Significance) subtypes of cervical tissue
-Dominant Fibroid (by diameter) >= 3 cm and <= 12 cm

Exclusion criteria

-Other Pelvic Disease (Other mass, endometriosis, ovarian tumour, acute pelvic disease)
-Desire for future pregnancy
-Significant systemic disease even if controlled (determined by intestigator or treating physician)
-Positive pregnancy test
-Hematocrit < 25%
-Extensive scarring along anterior lower abdominal wall (>50% of area)
-Scar tissue or surgical clips in the direct path of the HIFU beam
-MRI contraindicated
-MRI contrast agent contraindicated
-Fibroids not quantifiable on MRI (number & volume measurements)
-Calcifications around or throughout uterine tissues

-Communication Barrier

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-08-2009
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	MR guided High Intensity Focused Ultrasound
Registration:	No

Ethics review

Approved WMO

Date:	07-07-2009
Application type:	First submission
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
CCMO	NL27248.041.09