Minimal Invasive versus Non Invasive treatment for symptomatic uterine fibroids: A randomized controlled trial comparing uterine artery embolization with magnetic resonance guided focused ultrasound (MINI TRIAL)

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Uterine, pelvic and broad ligament disorders
Study type	Interventional

Summary

ID

NL-OMON35027

Source
ToetsingOnline

Brief title
MINI TRIAL

Condition

- Uterine, pelvic and broad ligament disorders

Synonym
uterine fibroids, uterine leiomyoma

Research involving

Human

Sponsors and support

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

Intervention

Keyword: minimal invasive treatment, MR guided focused ultrasound, uterine artery embolisation, uterine fibroids

Outcome measures

Primary outcome

The primary objective of the MINI-trial is to determine whether recovery is

quicker following MRgFUS than UAE. We measure recovery by using 2

questionnaires (QoR-40 and RI-10) and we determine the number of days needed to

return to work and normal activities.

Secondary outcome

-quality of life

-symptom improvement

-pain experience

-complications

-sexual functioning

-additional interventions

-ovarian function

-cost-effectiveness

Study description

Background summary

Uterine fibroids are common benign tumours in premenopausal women. Symptomatic fibroids influence women's health and quality of life in a negative way. A lot of women nowadays prefer a minimal invasive treatment over a surgical approach. The recovery is quicker and the complication rate is lower. Uterine artery embolization is a minimal invasive treatment with good clinical results. However, during the treatment and the post-treatment period pain experience can be very painful and prolong recovery. MR guided focused ultrasoudn (MRgFUS) is a new, completely non-invasive procedure for fibroids. MRgFUS uses ultrasoundwaves that ablate fibroid tissue in a specific location. The treatment is well tolerated and is performed in an outpatient setting. Recovery is quick and the complication risk is low.

Study objective

The objective of the MINI-trial is to compare the clinical effectiveness, quality of life, and cost-effectiveness of uterine artery embolisation (UAE) to MR guided focused ultrasound (MRgFUS) in pre- or perimenopausal women with symptomatic uterine fibroids.

Study design

Randomized controlled trial comparing MRgFUS with UAE. Patients will be randomized in a 1:1 ratio.

Intervention

Half of the patiens will undergo UAE according to the currently used protocol. The other half of the patients will undergo MRgFUS treatment. An ultrasound beam is used to generate high temperatures (50-70 degrees Celsius) very precisely in a specific target location. This results in well demarcated ares of necrosis within the focal area. Multiple ultrasound exposures are necessary to ablate the targeted tissue. Tight focusing is developed to limit the ablation to the targeted area.

Applying FUS energy to a fibroid requires treatment planning, targetting 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 methods for measuring the temperature increase generated by MRgFUS.

Study burden and risks

Screening:

-questionnaire symptoms and quality of life
-contrast enhanced MRI in prone position
-gynaecological and physical examination

Baseline:
-several questionnaires
-bloed tests + pregnancy test

Treatment MRgFUS:
-intravenous catheter
-catheter
-prone position in MRI scan during the procedure (max 4 hours)
-after treatment 2 hours observation before discharge

Treatment UAE:
-intravenous catheter
-profylactic antibiotics
-catheter
-PCA pump
-duration of procedure approximately 1,5 uur
-hospital stay for minimum of 1 night

Follow-up:
-patient diary
-2x visit gynaecologist
-2x contrast enhanced MRI scan
-2x bloed test
-questionnaires

Risks of MRgFUS:
-Potential complications after MRgFUS are nausea, pain, abdominal tenderness, and leg and buttock pain
-Less potential complications are swelling, 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 bleeding, injury to abdominal and pelvic organs (bladder, uterus, intestine), adverse drug reactions (gadolinium), fever due to infection. These complications are very rare.
-Unlikely complications are 2nd and 3rd degree skin burns.

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

-Minimum age of 18 years
-Patient is pre- or peri-menopausal
-Diagnosis of uterine fibroids is confirmed with MRI
-Patient suffers from symptomatic uterine fibroids (defined as a minimum Symptom Severity Score of 40 points)
-Patient must provide written informed consent

Exclusion criteria

-Uterine size larger than 24 weeks of gestation
-Dominant fibroid < 3 cm or > 12 cm diameter
-Pedunculated uterine fibroids with a stalk diameter less than one third of the fibroid diameter (MRI)
-Current pregnancy or desire for future pregnancy
-Suspected gynaecologic malignancy

-Extensive scarring along anterior lower abdominal wall
-Scar tissue or surgical clips in the direct path of the FUS beam
-Current gynaecologic infection
-Presence of intra uterine device
-Degenerated or calcified fibroids (evidenced by gadolinium non-enhancement on MRI)
-Contra-indications for MRI scanning (e.g. pacemaker, severe claustrophobia, ferromagnetic objects in the body)
-Contra-indications for the use of gadolinium based contrast agents (e.g. known allergy, or acute or chronic severe renal insufficiency (glomerular filtration rate <30 mL/min/1.73m2))
-Clinically relevant medical history or abnormal physical findings that could interfere with the safety of the participating patient as judged by the treating physician or the investigator

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	74
Type:	Anticipated

Medical products/devices used

Generic name:	MR guided focused ultrasound
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	09-02-2010
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL30162.008.09