# MYCHOICE: The MYoma treatment Comparison study: High intensity image guided fOcused ultrasound versus standard (minimally) Invasive fibroid care - a (Cost) Effectiveness analysis

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON25568

**Source**
NTR

**Brief title**
MYCHOICE

**Health condition**

Uterine fibroids, myomas, uterus myomatosus

### Sponsors and support

**Primary sponsor:** Isala Hospital Zwolle
**Source(s) of monetary or material Support:** Isala Hospital,
Medical Staff Board of Isala Hospital
Focused Ultrasound Foundation
Profound Medical

### Intervention

## Outcome measures

### Primary outcome

1.Quality of life (QoL) at the follow-up time point of 24 months after treatment;
2.Costs consisting of: direct health care costs, costs due to loss of productivity and patient costs.

### Secondary outcome

-Adverse events/complications;
-Length hospital stay;
-Peri/post procedural pain;
-Patient treatment preference and satisfaction;
-(Co)-medication;
-Re-interventions;
-Onset menopause;
-Reproductive outcomes;
-Non perfused volume, fibroid shrinkage.

# Study description

### Background summary

Our main objective is to determine long-term (cost)effectiveness of the MR-HIFU treatment in comparison to current standard (minimally) invasive fibroid care, i.e. UAE, myomectomy and hys-terectomy. By performing a two-armed RCT, we will provide the necessary data to prove that the MR-HIFU treatment fulfills the criteria needed to apply for reimbursement. Reimbursement of the MR-HIFU treatment will provide (eligible) women with symptomatic uterine fibroids a safe, sus-tainable, outpatient, non-invasive and uterus saving treatment option.

### Study objective

We hypothesize that in the Dutch healthcare setting:

1.The long-term effectiveness - primarily measured as disease specific QoL at 24 months after treatment - of the MR-HIFU treatment is non-inferior to standard (minimally) invasive fibroid care.
Previous studies and our own experience suggest that the change in disease specific QoL 24 months after the MR-HIFU treatment will be clinically relevant and comparable with the change in disease specific QoL 24 months after standard (minimally) invasive fibroid care.

2.MR-HIFU is cost-effective compared to standard (minimally) invasive fibroid care.

Standard (minimally) invasive fibroid care comprises treatments with a hospital stay, long recovery and a relatively high risk of adverse events and complications whereas MR-HIFU is an outpatient treatment with a low risk for adverse events and complications and short recovery. We expect that these benefits of MR-HIFU outweigh the possible additional costs for reinterventions after MR-HIFU, resulting in higher costs in the usual care group compared to MR-HIFU. With a compara-ble long-term effectiveness, we therefore expect MR-HIFU to be cost-effective compared to standard (minimally) invasive uterine fibroid care from a societal perspective.

### Study design

Baseline, 3 months follow-up, 6 months-follow-up, 12 months follow-up and 24 months follow-up

### Intervention

The intervention group will receive Magnetic Resonance image guided High Intensity Focused Ultrasound (MR-HIFU)
The control group can choose between standard care treatment, including: hysterectomy, myomectomy and uterine artery embolization (UAE)

## Contacts

**Public**
Isala Hospital
Martijn Boomsma

0031 88 624 5000
**Scientific**
Isala Hospital
Martijn Boomsma

0031 88 624 5000

## Eligibility criteria

### Inclusion criteria

• Symptomatic fibroids warranting (minimally) invasive treatment i.e. either hysterectomy, myomectomy or UAE;
• Conservative treatment failed or is undesired;

• Premenopausal;
• ≥18 years of age;
• Eligible for MR-HIFU treatment.

### Exclusion criteria

• Asymptomatic fibroids;
• Post-menopausal;
• BMI of ≥35kg/m2 and/or abdominal subcutis ≥4cm;
• >5 uterine fibroids unless 1 or 2 fibroids causing the symptoms can be clearly identified;
• MRI-contraindications or contrast allergy;
• Current pregnancy;
• Active child wish defined as desire for a pregnancy within one year after inclusion. These women will be excluded, because there is not yet consensus about the standard of care for these women. Women without active child wish but for whom a pregnancy in the future is not ruled out, can be included in the study;
• Suspicion of malignancy;
• Dominant adenomyosis, defined as more volume of adenomyosis rather than fibroids;
• Not willing to undergo pre-treatment with Leuproreline (Lucrin) before MR-HIFU in case of a uterine fibroid with a diameter >10cm or classified as Funaki 3;
• Not willing to remove an interfering intra-uterine contraception device (Mirena) prior to MR-HIFU;
• Not willing or able to give informed consent;
• Not eligible for MR-HIFU as determined by the multidisciplinary MR-HIFU team in Isala based on a screening MRI:
- Uterine fibroid(s) classified with FIGO classification 0-1 or 8 or with a diameter <2 cm;
- Fibroids suitable for hysteroscopical removal;
- Distance abdominal wall to dorsal side of uterine fibroids expected to be >12cm even after use of manipulation techniques;
- Calcified uterine fibroids or fibroids without contrast enhancement.

## Study design

### Design

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 25-11-2020 |
| Enrollment: | 240 |
| Type: | Anticipated |

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion

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|---|---|
| Date: | 31-08-2020 |
| Application type: | First submission |

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 55295
Bron: ToetsingOnline
Titel:

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

| Register | ID |
|---|---|
| NTR-new | NL8863 |
| CCMO | NL74716.075.20 |
| OMON | NL-OMON55295 |

# Study results