# The hysteroscopic morcellator versus the bipolar resectoscope for removal of submucous myomas: a randomized controlled trial.

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To compare the HM to bipolar resectoscopy for removal of smaller type 0 and 1 myomas in terms of efficiency and complications.

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

## Summary

### ID

NL-OMON37929

**Source**
ToetsingOnline

**Brief title**
Hysteroscopic morcellator versus bipolar resectoscope for myomectomy

### Condition

- Reproductive neoplasms female benign
- Uterine, pelvic and broad ligament disorders

**Synonym**
benign tumour of the womb, submucous myoma

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Catharina-ziekenhuis

**Source(s) of monetary or material Support:** geen financiering

## Intervention

**Keyword:** hysteroscopic morcellator, operating time, operative hysteroscopy, submucous myoma

## Outcome measures

### Primary outcome

Installation and operation time.

### Secondary outcome

Comparing data on peri- and post operative complications (e.g. fluid deficit,

conversion rates, perforation, burns, postoperative infection), availability of

tissue for pathology analysis and pathology results, and efficiency at 6 weeks

follow-up.

# Study description

### Background summary

The hysteroscopic morcellator (HM) is a novel technique for removal of intrauterine myomas, that withholds some technical advantages over resectoscopy. Previous data suggest that it*s a faster technique than the latter, and shows that it has a low complication rate.

### Study objective

To compare the HM to bipolar resectoscopy for removal of smaller type 0 and 1 myomas in terms of efficiency and complications.

### Study design

Single blind, randomized controlled trial.

### Intervention

Patients are randomized between removal with the HM or the bipolar

resectoscope.

**Study burden and risks**

Women who are referred to our polyclinic will be seen on a first visit, and, according to the standard work-up, an ultrasound will be performed when an intrauterine myoma is suspected. To confirm the diagnosis a saline infusion sonography (SIS) and/or ambulant diagnostic hysteroscopy will be performed consequently. Once the diagnosis is confirmed and surgery is planned, women will be asked whether they want to take part in this study. At this moment, both techniques are used in our hospital and the choice of treatment depends on the preference of the gynecologist. All women will be treated with operative hysteroscopy in a daycare setting according to the standard of care, only now randomized between the two techniques. A standard postoperative visit with ultrasound examination is scheduled 6 weeks later. Late postoperative complications and complaints are recorded.
It is expected that the HM beholds some advantages over the bipolar resectoscope such as shorter operation time and less complications (e.g. risk of perforation, current and fluid related complications). Previous data do not demonstrate any additional risks related to the use of the HM.

# 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

Patients with one or more intrauterine myoma(s) with a diameter <= 3 cm as seen on ultrasound, confirmed by saline infusion sonography and/or ambulant diagnostic hysteroscopy who are planned for hysteroscopic surgery.

## Exclusion criteria

Patients with:
• Myomas with a diameter > 3 cm (Note: Myomas > 3 cm are treated with resectoscopy)
• Type 2 myomas
• Visual or pathological (e.g. on biopsy) evidence of malignancy preoperatively or at the time of operation.
• Untreated cervical stenosis making safe access for operative hysteroscopy impossible as diagnosed preoperatively or at the time of operation.
• A contra-indication for operative hysteroscopy.

# Study design

## Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | Active |
| Primary purpose: | Treatment |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 20-04-2011 |
| Enrollment: | 37 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 18-01-2011 |
| Application type: | First submission |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 19-03-2012 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |

## 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 | NL34639.060.10 |