# Comparison of hand or motor driven hysteroscopic removal systems

No registrations found.

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

## Summary

### ID

NL-OMON21102

**Source**
Nationaal Trial Register

**Brief title**
REMOvE 9 (REsectr (9fr) for the MOrcellation of Endometrial polyps)

**Health condition**

- polyp
- hysteroscopy
- Minimally Invasive Surgical Procedures

### Sponsors and support

**Primary sponsor:** Catharina Hospital Eindhoven
Ghent University Hospital
**Source(s) of monetary or material Support:** Boston Scientific

### Intervention

### Outcome measures

**Primary outcome**

Primary Objective: Comparing installation and operating time between the Truclear HM device and the Resectr® 9.0 fr HM device for removal of intrauterine large polyps.

### Secondary outcome

Secondary Objective(s): Comparing data on procedure time, peri- and postoperative complications (e.g. fluid deficit, conversion rates, perforation), postoperative availability of tissue for pathology analysis and pathology diagnosis, pain scores, evaluation of surgeons convenience during procedures and efficiency (completeness of resection and persistence of symptoms or abnormalities at 6 weeks follow-up).

## Study description

### Background summary

Nowadays, the hysteroscopic morcellator (HM) is a widely used technique for removal of intrauterine polyps. Various mechanical, motor-driven tissue removal systems are used in clinical setting (Truclear; Medtronic, Minneapolis Minnesota, MyoSure; Hologic, Bedford, MA and Bigatti;Karl Storz Tuttlingen, Germany). Recently, a new mechanical, hand-driven device was launched (Resectr®; Boston Scientifc, Marlborough, MA). It has advantages due to the simplicity and low costs. Furthermore, in vitro testing shows similar resection speed as the motorized device. This study wants to compare the resection speed of two different devices for removal of polyps (≥8mm, ≤20 mm) in terms of efficiency and complications.

### Study objective

To compare the resection speed of two different devices for removal of polyps (≥8mm - ≤20 mm) in terms of efficiency and complications.

### Study design

- diagnosis intrauterine polyps
- confirmation by ultrasound, saline infusion sonography and/or ambulant diagnostic hysteroscopy
- inclusion in study
- randomisation and removal of polyps
- 6 weeks post operation: follow-up

### Intervention

-Group 1: removal of intrauterine polyps with Truclear hysteroscopic morcellator
-Group 2: removal of intrauterine polyps with Resectr hysteroscopic morcellator

# Contacts

**Public**
Catharina Hospital Eindhoven
Dick Schoot
C. Heymanslaan 10

Gent 9000
Belgium
+31 6 51 54 70 41
**Scientific**
Catharina Hospital Eindhoven
Dick Schoot
C. Heymanslaan 10

Gent 9000
Belgium
+31 6 51 54 70 41

# Eligibility criteria

## Inclusion criteria

- endometrial polyps largest diameter ≥8mm - ≤20 mm
- intrauterine polyps confirmed by ultrasound, saline infusion sonography and/or ambulant diagnostic hysteroscopy

## Exclusion criteria

• Polyps largest diameter smaller than 8 mm
• Polyps largest diameter larger than 20 mm
• 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
• Significant language barrier
• Pregnant women

# Study design

## Design

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

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-09-2018 |
| Enrollment: | 140 |
| Type: | Anticipated |

## IPD sharing statement

**Plan to share IPD:** Undecided

# Ethics review

Positive opinion

| | |
|---|---|
| Date: | 27-03-2018 |
| Application type: | First submission |

# 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 |
|---|---|
| NTR-new | NL6922 |
| NTR-old | NTR7118 |
| Other | Catharina Hospital Eindhoven : EC/2017/1576 |

# Study results