

The hysteroscopic morcellator versus the bipolar resectoscope for removal of larger intrauterine polyps: a randomized controlled trial.

Published: 18-01-2011

Last updated: 04-05-2024

To compare the HM to bipolar resectoscopy for removal of large intrauterine polyps in terms of efficiency and complications.

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

Summary

ID

NL-OMON38073

Source

ToetsingOnline

Brief title

Hysteroscopic morcellator versus bipolar resectoscope for polypectomy

Condition

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

Synonym

endometrial polyp, swelling of the inner lining of the womb

Research involving

Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis

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

Intervention

Keyword: endometrial polyp, hysteroscopic morcellator, operating time, operative hysteroscopy

Outcome measures

Primary outcome

Installation and operating 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 polyps, 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 large intrauterine polyps 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 polyp 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 operating 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

Public

Catharina-ziekenhuis

Postbus 1350
5602 ZA Eindhoven
NL

Scientific

Catharina-ziekenhuis

Postbus 1350
5602 ZA Eindhoven
NL

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 polyp(s) with a diameter ≥ 1 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:

- Only polyps < 1 cm (Note: intrauterine polyps < 1 cm are treated in an ambulatory setting).
- 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.
- With a contra-indication for operative hysteroscopy.

Study design

Design

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

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated):	27-07-2011
Enrollment:	37
Type:	Actual

Ethics review

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	NL33773.060.10