Clinical evaluation of a new hand driven hysteroscopic tissue removal device, Resectr 5fr, for the resection of endometrial polyps in an office setting.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23197

Source
NTR

Brief title
REMOvE 5 (REsectr (5fr) for the MOrcellation of Endometrial polyps in an office setting)

Health condition

- polyp
- hysteroscopy
- Minimally Invasive Surgical Procedures

Sponsors and support

Primary sponsor: Benedictus Christiaan Schoot MD PhD
Department of Obstetrics and Gynaecology
Catharina Hospital Eindhoven

Source(s) of monetary or material Support: Boston Scientific

Intervention

Outcome measures

Primary outcome

Installation and resection time (of the largest polyp)

Secondary outcome

o Surgeon’s convenience on a 5-point Likert scale
o Patient’s pain and satisfaction score on a 5-point Likert scale
o Intra- and postoperative complications (fluid deficit, blood loss (≥ 500ml), uterine perforation, infection)
o Completeness of resection (separation and extraction of all visible polyp tissue)
o Short term effectiveness (persistence of symptoms at 6 week follow-up)
o Postoperative availability of tissue for pathology analysis and pathology diagnosis

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. The small 5.0 fr variant can be used in the outpatient setting. In this study the investigator wants to acquire information concerning the resection speed of the Resectr® 5.0 fr device for the removal of small polyps (mean diameter ≤ 8 mm) in terms of efficiency and complications.
Study design: Prospective multicenter trial.

Study objective

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. The small 5.0 fr variant can be used in the outpatient setting.

Study design

- diagnosis of intrauterine polyps
- confirmation by saline infusion sonography and/or diagnostic hysteroscopy
- inclusion in study
- hysteroscopic polypectomy using Resectr® 5.0 fr.
- 6 weeks after the operation: follow-up visit or telephone contact

Intervention

Hysteroscopic polypectomy using the hand driven tissue removal device Resectr® 5.0 fr. in an office setting without anesthesia

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

Patients of 18 years or older, with one or more intrauterine polyp (mean diameter 8mm or smaller) as seen on ultrasound, saline infusion sonography and/or ambulant diagnostic hysteroscopy who are planned for hysteroscopic surgery in an outpatient setting.

Exclusion criteria

• Polyps > 8 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:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2018
Enrollment:	112
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	NL6923
NTR-old	NTR7119
Other	Catharina Hospital : 2017/1577

Study results