The hand driven hysteroscopic tissue removal system (Resectr 9Fr) versus motor driven hysteroscopic tissue removal system (Truclear) for removal of polyps: A randomized controlled trail.

Published: 25-04-2019
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Primary Objective: Comparing installation and operating time between the Truclear HM device and the Resectr HM device for removal of intrauterine large polyps.Secondary Objective(s): Comparing data on peri- and post operative complications (e.g.…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Menstrual cycle and uterine bleeding disorders
Study type	Interventional

Summary

ID

NL-OMON55576

Source
ToetsingOnline

Brief title
Comparison of hand and motor driven hysteroscopic removal systems

Condition

- Menstrual cycle and uterine bleeding disorders

Synonym
benign uterine growth, polyp

Research involving
Human

Sponsors and support

Primary sponsor: UZ Gent
Source(s) of monetary or material Support: Boston Scientific;unrestricted grant

Intervention

Keyword: Hysteroscopy, Hystroscopic removal systems, Polyps

Outcome measures

Primary outcome

Installation time and resection/ operating time.

Secondary outcome

Fluid deficit, conversion rates, peri- and postoperative complications,

availability of tissue for pathology, persistence of symptoms (e.g.

menorrhagia) and/or intrauterine abnormalities at 6 weeks follow-up, pain

scores and evaluation of surgeons convenience during procedures.

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.

Study objective

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

Secondary Objective(s): Comparing data on peri- and post operative 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 design

Single-blind randomized controlled trial comparing the Truclear HM with Resectr HM device in operative hysteroscopy. Patients are not aware of the technique used. The duration of the study is estimated at 2 years based on operating data of the last 4 years in our center. The study will be performed in the Department of Gynecology in our university-affiliated teaching hospital, Catharina Hospital Eindhoven, the Netherlands and in the department of OB GYN UZ Gent Belgium

Intervention

Hystroscopisic tissue removal (polyp removal)

Study burden and risks

We do acknowledge certain disadvantages of the Resectr and Truclear. The inability to coagulate bleeding vessels encountered during surgery might be a disadvantage. However, so far, no significant intraoperative or postoperative bleeding was documented. Secondly, both techniques cannot be used for the treatment of submucous fibroids. However, in the work-up of operative hysteroscopy polyps can clearly be diagnosed.

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 polyps (largest diameter >=8 mm - <= 20mm).as seen on ultrasound, confirmed by saline infusion sonography and/or ambulant diagnostic hysteroscopy
- Planned for hysteroscopic surgery.

Exclusion criteria

Patients with:
• Polyps <8 mm or > 20mm
• 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

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):	02-04-2018
Enrollment:	80
Type:	Actual

Medical products/devices used

Generic name:	Hand driven hysteroscopic tissue removal system (Resectr 9Fr)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	25-04-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	19-12-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	08-12-2021
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
Other	Nederlands Trial Register (NL 6922)
CCMO	NL63142.100.18