The hand driven hysteroscopic tissue removal system (Resectr® 9.0 fr) versus motor driven hysteroscopic tissue removal system (Truclear) for removal of polyps: a randomized controlled trial.

No registrations found.

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

Summary

ID

NL-OMON25363

Source
Nationaal Trial Register

Brief title
RESECTR

Health condition

- polyp
- hysteroscopy
- Minimally Invasive Surgical Procedures

Sponsors and support

Primary sponsor: Stichting research foundation Gynaecology, represented by Benedictus Christiaan Schoot
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 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

To compare the resection speed of two different devices for removal of large polyps (larger than 8mm up to 20mm) in terms of efficiency and complications.

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.

Study design

-Screening: women wih an ultrasound suggestive for intrauterine polyps

-saline infusion sonography or diagnostic hysteroscopy confirm diagnosis of polyp larger than 8mm

-Randomisation (Truclear or Resectr) and removal of polyp

-Follow-up visit 6 weeks post-op with ultrasound

Intervention

Patients are randomized between removal with the HM using Truclear and the hand driven device Resectr® 9.0 french (fr).

Contacts

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Eligibility criteria

Inclusion criteria

-Women of any ethnic background aged min. 18 years, attending our outpatient clinic with an intrauterine polyp

-Patients with one or more intrauterine polyps (larger than or equal to 8 mm up to 20mm) as seen on ultrasound, confirmed by saline infusion sonography and/or ambulant diagnostic hysteroscopy who are planned for hysteroscopic surgery.

Exclusion criteria

• Polyps smaller than 8 mm

• Polyps 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):	09-01-2018
Enrollment:	120
Type:	Anticipated

Ethics review

Positive opinion

Date:	20-03-2018
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	NL6908
NTR-old	NTR7103
Other	Ethische comité : EC/2017/1576

Study results