MUST: Morcellation and Uterine Snare Resection Trial

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22926

Source
NTR

Brief title
MUST

Health condition

Duckbill polyp snare, hysteroscopic morcellator, endometrial polyp, outpatient polypectomy

Sponsors and support

Primary sponsor: Maxima Medisch Centrum Veldhoven
Source(s) of monetary or material Support: fund = initiator - sponsor

Intervention

Outcome measures

Primary outcome

Complete removal of the polyp

Secondary outcome

patient acceptance and pain.

operating time

complications

recurrence of polyps within one year

Study description

Background summary

Endometrial polyps occur in both pre- and postmenopausal women and are often asymptomatic. When symptoms occur they most commonly include abnormal uterine bleeding. The vast majority of polyps are benign with a prevalence of atypia and malignancy of 0.8% and 3.1% respectively.
The first choice treatment for endometrial polyps is hysteroscopic resection. The miniaturisation of hysteroscopes and ancillary instrumentation coupled with enhanced visualisation has enabled hysteroscopic surgery to be performed in an outpatient setting without the need for general anesthesia. The removal of endometrial polyps with the Duckbill snare as an office procedure has first been described in 2005. Whilst the technology is feasible and effective it requires skills and experience in outpatient hysteroscopic surgery, which many gynecologists lack and this is reflected in the limited adoption of polyp snare procedures. The limited adoption can additionally be explained by to lack of publications supporting their use for the removal of endometrial polyps. The Duckbill polyp snare has been investigated in two studies, which showed the snare is a safe and efficient method and is well tolerated by patients.
In 2005 a new technology has become available called the hysteroscopic morcellator. Two recently conducted randomized controlled trials showed an overall efficacy of 92-98%.

The Duckbill polyp snare has two important advantages over the hysteroscopic morcellator. The snare can be used down the operating channel of a variety of continuous flow hysteroscopes, which are already being used in day-to-day use in gynaecological practice in outpatient settings. In contrast, the hysteroscopic morcellator system requires acquisition of specific hysteroscopes. Another advantage are the costs of the device, which are about six times lower for the Duckbill polyp snare in comparison with the hysteroscopic morcellation with a purchase price of respectively 55 euro and 304,32 euro.

Studies in which the hysteroscopic morcellator is compared with the Duckbill polyp snare are lacking therfore it is uncertain which method is the first choice method to remove endometrial polyps in an outpatient setting.

In this study we hypothesize that snare resection is non-inferior to hysteroscopic morcellation (primary outcome).

This is a multicenter trial which will be performed in the Netherlands.

Study objective

Snare resection is non-inferior to hysteroscopic morcellation and snare resection is cost-effective.

Study design

The primary outcome, completeness of polyp removal, will be analysed by logistic regression. We will adjust for confounders if necessary. To show non-inferiority the upper bound of the 95% CI for the difference in completeness of polyp removal should not exceed the prespecified non-inferiority margin of 10%.

Standard statistical methods will be used to analyse secondary outcomes.

Subgroup analyses based on the size of the polyp will be made as size influences the completeness of removal.
Analyses for all parameters will be by intention to treat. We will also perform a per protocol analysis, considering the non-inferiority design of the study.

We expect the effect on the quality of life will be comparable between the two procedures as we expect the Duckbill polyp snare to be non-inferior in the resection of polyps as compared to the hysteroscopic morcellator.

Intervention

Transcervical resection of polyps with the Duckbill polyp snare

Contacts

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Eligibility criteria

Inclusion criteria

All consenting women with benign looking endometrial polyps

Exclusion criteria

Women with malign looking endometrial polyps.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2016
Enrollment:	220
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

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	NL5462
NTR-old	NTR5606
Other	ZonMW : ProjectNetAanvraag55208

Study results

Summary results
Beelen P, Geomini PMAJ, Veersema S, Bongers MY. Hysteroscopic resection of endometrial polyps using the Duckbill Polyp Snare in an outpatient setting.2015. Unpublished.