The hysteroscopic morcellator versus the bipolar resectoscope for removal of residual placental tissue: a randomized controlled trial.

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To compare the HM to bipolar resectoscopy for removal of residual placental tissue in terms of efficiency and complications.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Placental, amniotic and cavity disorders (excl haemorrhages)
Study type	Interventional

Summary

ID

NL-OMON38083

Source
ToetsingOnline

Brief title
Hysteroscopic morcellator versus bipolar resectoscope: placental tissue

Condition

- Placental, amniotic and cavity disorders (excl haemorrhages)
- Uterine, pelvic and broad ligament disorders

Synonym
remainders of the afterbirth in the womb, residual placental tissue

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis

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

Intervention

Keyword: hysteroscopic morcellator, operating time, operative hysteroscopy, residual placental tissue

Outcome measures

Primary outcome

Installation and operating time.

Performing a second look hysteroscopy after 6 weeks checking for intrauterine

adhesions, comparing the 2 techniques.

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 lesions such as myomas, polyps and residual placental tissue. It 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. Data on removal of residual placental tissue by repetition of curettage show a high risk of adhesion formation.

Study objective

To compare the HM to bipolar resectoscopy for removal of residual placental tissue 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 residual placental tissue is suspected. To confirm the diagnosis an 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 postoperative visit with second look hysteroscopy, checking for intrauterine adhesions, 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. Moreover we will check whether the HM has a lower risk of intrauterine adhesion formation, as this might influence patient*s fertility.

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 residual placental tissue as seen by ambulant diagnostic hysteroscopy who are planned for hysteroscopic surgery.

Exclusion criteria

Patients with:
• 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.

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):	04-05-2011
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	NL34646.060.10