Surgical treatment of placental remnants: hysteroscopic morcellation versus ultrasound guided electric vacuum aspiration, a multicenter randomized controlled trial

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To compare HM to ultrasound guided electric vacuum aspiration (EVA) for removal of placental remnants with respect to the risk of IUA formation, and in terms of efficiency and complications.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Postpartum and puerperal disorders
Study type	Interventional

Summary

ID

NL-OMON50222

Source
ToetsingOnline

Brief title
PLACEMTA: PLAcental remnants CurEttage hysteroscopic Morcellation TriAl

Condition

- Postpartum and puerperal disorders
- Obstetric and gynaecological therapeutic procedures

Synonym
placental remnants or residual trophoblastic tissue

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: geen financiering tot op heden

Intervention

Keyword: curettage, hysterocopy, placental remnants, vacuum aspiration

Outcome measures

Primary outcome

IUA at follow-up.

Secondary outcome

- Installation and operating time

- Conversion rates

- Peri- and postoperative complications (e.g. excessive fluid deficit in case

of hysteroscopy, perforation, hemorrhage, postoperative infection)

- Availability of tissue for pathology analysis and pathology results

- Completeness of removal at second look hysteroscopy

- Persistence of symptoms

- Necessity for additional treatment

- Reduction of unnecessary interventions

Study description

Background summary

Placental remnants can occur following miscarriage, termination of pregnancy (TOP), after vaginal delivery or cesarean section. Placental remnants are mainly removed by curettage, however data suggest that hysteroscopic removal might be superior to curettage regarding completeness of removal, tissue availability, the risk of development of intrauterine adhesions (IUA) and in

reducing unnecessary interventions. To our knowledge no randomized controlled trials have been published comparing removal of remnants by hysteroscopic morcellation (HM) versus curettage.

Study objective

To compare HM to ultrasound guided electric vacuum aspiration (EVA) for removal of placental remnants with respect to the risk of IUA formation, and in terms of efficiency and complications.

Study design

Multicenter, randomized controlled trial with prospective follow up of patients with a placental remnant who do not wish to participate in the randomized controlled trial

Intervention

Patients are randomized between HM or ultrasound guided EVA.
Patients in the observational prospective study will receive the treatment of their choice: HM or ultrasound guided EVA.

Study burden and risks

Women who attend our outpatient clinic will be seen on a first visit, and, according to the standard work-up, an ultrasound will be performed when placental remnants are suspected. Patients with placental remnants according to the ultrasonographic inclusion criteria are asked whether they want to take part in this study after discussion of the different treatment options. After informed consent, patients are randomized between EVA and HM. Patients who are randomized for EVA can undergo this procedure as soon as possible, as this is common practice. Patients in the hysteroscopic treatment arm first undergo an ambulant diagnostic hysteroscopy at a minimum of 6 weeks after end of pregnancy to confirm the diagnosis of placental remnants. Upon confirmation a HM procedure is scheduled approximately 1 week later. At this moment, both hysteroscopic removal and vacuum aspiration are used in our hospitals and the choice of treatment depends on the preference of the gynecologist. All women will be treated 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 and completeness of removal, is scheduled after at least 1 menstruation or a period of minimum 8 weeks after the operation. Late postoperative complications and complaints are recorded.
Aim of the study is to examine whether HM beholds advantages over ultrasound guided EVA in terms of a lower risk of IUA formation and more complete removal, as these often require additional treatment and may influence patient*s future

fertility.
Patients who do not want to participate in the randomized trial are asked whether they consent with follow-up in the prospective cohort study.

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

Ultrasonographic findings: image suggestive for placental remnants ranging from 1 to 4 cm in diameter

Exclusion criteria

Placental remnants with a maximum diameter smaller than 1 cm or more than 4 cm
Patients presenting with fever
Visual or pathological (e.g. on biopsy) evidence of malignancy preoperatively or at the time of operation
Untreated cervical stenosis making safe uterine access impossible as diagnosed preoperatively by ambulant hysteroscopy
A contra-indication for surgery

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-03-2015
Enrollment:	95
Type:	Actual

Ethics review

Approved WMO Date:	18-06-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-02-2015
Application type:	Amendment

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-04-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-09-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-10-2022
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	NL47365.060.13