Placental remnants curettage hysteroscopic morcellation trial

No registrations found.

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

Summary

ID

NL-OMON27293

Source
Nationaal Trial Register

Brief title
PLACEMTA

Health condition

placental remnants
retained products of pregnancy
residual trophoblastic tissue
retained products of conception
retained placental tissue
hysteroscopy
hysteroscopic morcellation
vacuum aspiration

Sponsors and support

Primary sponsor: Catharina Hospital Eindhoven
Ghent University Hospital
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

Intrauterine adhesions diagnosed by second look hysteroscopy after at least 1 menstruation or a period of minimum 8 weeks after the operation.

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
- Subsequent reproductive and pregnancy outcome

Study description

Background summary

Rationale: 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, and the risk of development of intrauterine adhesions (IUA). 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.

Study population: Women aged over 18 years old with placental remnants measuring 1 to 4 cm, after miscarriage, termination of pregnancy (TOP) or delivery.

Intervention: Patients are randomized between HM or ultrasound guided EVA.

Main study parameters/endpoints: IUA at follow-up. 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. With their 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. Upon confirmation a HM procedure is scheduled approximately 1 week later. 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. Subsequent reproductive and pregnancy outcomes will also be studied.

Addendum 6-dec-2015:
Main changes: Patients who do not want to participate in the randomized trial are asked whether they consent with follow-up in the prospective cohort study, and they receive the treatment of their choice. Subjects that withdraw from the study preoperatively will have no follow-up within the study, but will receive standard follow-up and treatment outside of the study. With their consent they can be followed-up in the prospective cohort study.

Study objective

Hysteroscopic morcellation of placental remnants has a lower risk of postoperative intrauterine adhesion formation compared to ultrasound guided electric vacuum aspiration.

Study design

- Outpatient clinic: diagnosis retained product of pregnancy. randomization to:

A. vacuum aspiration asap or

B. 6 weeks after termination of pregnancy diagnostic hysteroscopy. confirmation placental remnant then hysteroscopic morcellation

- Second look hysteroscopy 8 weeks after surgery or 1 menstruation

Intervention

hysteroscopic morcellation

ultrasound guided electric vacuum aspiration

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Age at least 18 years

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

- Willing to give informed consent

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- 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:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2015
Enrollment:	140
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	23-11-2014
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	NL4784
NTR-old	NTR4923
Other	- : M14-1409

Study results

Summary results

- Golan A, Dishi M, Shalev A, Keidar R, Ginath S, Sagiv R. Operative hysteroscopy to remove retained products of conception: novel treatment of an old problem. J. Minim. Invasive Gynecol. 2001;18(1):100–3.

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- Cohen SB, Kalter-Ferber A, Weisz BS, Zalel Y, Seidman DS, Mashiach S, et al. Hysteroscopy may be the method of choice for management of residual trophoblastic tissue. J. Am. Assoc. Gynecol. Laparosc. 2001;8(2):199–202.

- Dankert T, Vleugels M. Hysteroscopic resection of retained placental tissue: a feasibility study. Gynecol. Surg. 2008;5:121–4.

- Faivre E, Deffieux X, Mrazguia C, Gervaise A, Chauveaud-Lambling A, Frydman R, et al. Hysteroscopic management of residual trophoblastic tissue and reproductive outcome: a pilot study. J. Minim. Invasive Gynecol. 2009;16(4):487–90.

- Nicopoullos JDM, Treharne A, Raza A RR. The use of a hysteroscopic resectoscope for repeat evacuation of retained products of conception procedures: a case series. Gynecol. Surg. 2010;7:163–6.

- Rein DT, Schmidt T, Hess AP, Volkmer A, Schöndorf T, Breidenbach M. Hysteroscopic management of residual trophoblastic tissue is superior to ultrasound-guided curettage. J. Minim. Invasive Gynecol. 2011;18(6):774–8.

- Kuzel D, Horak P, Hrazdirova L, Kubinova K, Sosna O, Mara M. “See and treat” hysteroscopy after missed abortion. Minim. Invasive Ther. Allied Technol. 2011;20(1):14–7.