Placental remnants curettage hysteroscopic morcellation trial

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27293

Bron
Nationaal Trial Register

Verkorte titel
PLACEMTA

Aandoening

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

Ondersteuning

Primaire sponsor: Catharina Hospital Eindhoven
Ghent University Hospital
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

- 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

Onderzoeksproduct en/of interventie

hysteroscopic morcellation

ultrasound guided electric vacuum aspiration

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2015
Aantal proefpersonen:	140
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	23-11-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4784
NTR-old	NTR4923
Ander register	- : M14-1409

Resultaten

Samenvatting resultaten

- 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.

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- 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.

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- 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.