Diagnostic value of saline infused sonography compared to hysteroscopy in detecting retained products of conception.

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We expect that the test characteristics of saline infusion sonography will be higher than the test characteristics of the transvaginal ultrasound. We expect that the saline infusion sonography is less painful and has a lower complication rate than...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29567

Bron
NTR

Verkorte titel
PLACENSIS

Aandoening

Retained products of conception

Ondersteuning

Primaire sponsor: Catharina Ziekenhuis Eindhoven
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The aim of this study is to compare the test characteristics (sensitivity, specificity, positive and negative predictive value) of SIS with hysteroscopy for the diagnosis of RPOC.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Retained products of conception (RPOC) can occur following miscarriage, termination of pregnancy (TOP) or delivery with a prevalence of 1% (1). Symptoms are vaginal bleeding, uterine tenderness, pelvic pain and fever. Treatment consists of curettage or hysteroscopic removal. The gold standard for the diagnosis of RPOC is hysteroscopy. A less invasive method is transvaginal ultrasound (TVUS), however, the sensitivity and specificity of this diagnostic test are lower and vary among studies (respectively 44-93% and 74-92%). Data suggest that the test characteristics of saline infused sonography (SIS) might be higher. SIS is often used to diagnose polyps and myomas. Studies have demonstrated that this method is less painful than hysteroscopy. For the diagnosis of polyps and myomas, SIS also provides better test characteristics compared to TVUS. For these reasons, we want to compare the test characteristics of TVUS, SIS and hysteroscopy for diagnosing RPOC.
Objective: The main objective is to compare the test characteristics (sensitivity, specificity, positive and negative predictive value) of SIS with hysteroscopy for the diagnosis of RPOC. Secondary objectives are the complications related to the diagnostic methods, the characteristics of hysteroscopic removal of RPOC and interobserver variability of the diagnostic procedures.

Study design:
Prospective diagnostic study

Study population:
Women over 18 years old with suspicion of RPOC after miscarriage, TOP or delivery.

Intervention:
All patients are examined by TVUS, SIS and diagnostic hysteroscopy. RPOC will be classified according to the Gutenberg classification. Subsequently a hysteroscopic removal of RPOC is performed in every patient with the diagnosis of RPOC confirmed by diagnostic hysteroscopy at a minimum of 5 weeks after pregnancy.

Main study parameters/endpoints:
Sensitivity and specificity, positive and negative predictive value SIS compared to diagnostic hysteroscopy for the diagnosis of RPOC.

Nature and extent of the burden and risks associated with participation, benefit and group

relatedness:
Women who visit our outpatient clinic will be seen on a first visit and, according to the standard work-up, an TVUS will be performed when RPOC are suspected. Patients with suspicion of RPOC according to the TVUS are asked whether they want to take part in this study. Patients are counselled about SIS and diagnostic hysteroscopy. With their consent, patients are planned in at a minimum of 5 weeks after pregnancy for TVUS, SIS and ambulant diagnostic hysteroscopy. All diagnostic procedures take place on the same day. Subsequently hysteroscopic removal is performed in every patient with a diagnosis of RPOC confirmed by diagnostic hysteroscopy, according to standard care. All women will be treated in a standard daycare setting. 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 (standard care). Late postoperative complications and complaints will be recorded.

Doel van het onderzoek

We expect that the test characteristics of saline infusion sonography will be higher than the test characteristics of the transvaginal ultrasound. We expect that the saline infusion sonography is less painful and has a lower complication rate than hysteroscopy.

Onderzoeksopzet

Primary outcomes:
At a minimum of 5 weeks after pregnancy a TVUS, SIS and ambulant diagnostic hysteroscopy will be performed. All diagnostic procedures take place on the same day. The primary endpoints (sensitivity, specificity, positive and negative predictive value) will be defined by comparison with the golden standard diagnostic test (hysteroscopy).

Secondary outcomes:
After the diagnostic test, the patient will be asked about VAS-score and patient satisfaction. Complications of the diagnostic test will be recorded after performing each test. Characteristics of the hysteroscopic treatment will be recorded after performing the operative hysteroscopy and at the postoperative visit with second look hysteroscopy. Interobserver variability of the diagnostic procedures will be examined after performing all the tests.

Onderzoeksproduct en/of interventie

A saline infusion sonography will be performed

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 ≥ 18 years
- Ultrasound suggestive of RPOC
- 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: Patients presenting with fever or heavy menstrual bleeding in need of immediate surgical treatment.
Patients with negative findings at ambulant diagnostic hysteroscopy will not be treated with operative hysteroscopy as treatment is then no longer necessary. Data on this matter will be collected. Only patients with confirmation of RPOC by ambulant diagnostic hysteroscopy at a minimum of 5 weeks after the end of pregnancy will be treated.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-04-2021
Aantal proefpersonen:	186
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	17-02-2021
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	NL9297
Ander register	MEC-U : R21.014

Resultaten