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

Published: 17-06-2021
Last updated: 13-05-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Observational invasive

Summary

ID

NL-OMON54309

Source
ToetsingOnline

Brief title
PLACENSIS

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
placental remnants

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis

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

Intervention

Keyword: Diagnostic value, retained products of conception (RPOC), saline infused sonography (SIS)

Outcome measures

Primary outcome

Sensitivity and specificity, positive and negative predictive value of SIS

compared to diagnostic hysteroscopy for the diagnosis of RPOC.

Secondary outcome

- Comparison of the diagnostic methods (TVUS, SIS and hysteroscopy) in terms of

VAS-score; patient satisfaction, complications

- Characteristics of the hysteroscopic treatment of RPOC

- Interobserver variability of the diagnostic tests

Study description

Background summary

Retained products of conception (RPOC) can occur following miscarriage, termination of pregnancy (TOP) or delivery with a prevalence of 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.

Study 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 the interobserver variability of the diagnostic tests.

Study design

Prospective diagnostic study

Study burden and risks

TVUS is currently the most widely performed diagnostic test for RPOC but has poor test characteristics. Data suggest that the test characteristics of SIS might be higher. SIS is often performed at a gynaecological unit, e.g. in diagnosing polyps and myomas.
One of the benefits is definitive diagnosis of RPOC by diagnostic hysteroscopy, which can help to avoid unnecessary treatment.
Risks for patients are considered low and include complications related to SIS (postprocedural fever 0.78% bleeding) and related to diagnostic hysteroscopy (perforation 0,13%, infection 0,06%, bleeding).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Age >= 18 years
- Ultrasound suggestive of RPOC

Exclusion criteria

Patients presenting with fever or heavy menstrual bleeding in need of immediate surgical treatment.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-04-2022
Enrollment:	186
Type:	Actual

Ethics review

Approved WMO Date:	17-06-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-01-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-02-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-05-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-08-2023
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	NL76577.100.21
Other	NL9297