Het voorkomen van littekenvorming in de baarmoeder bij vrouwen die een curettage ondergaan vanwege een miskraam. (Evaluatie van anti-verklevingsmiddel).

No registrations found.

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

Summary

ID

NL-OMON22431

Source
NTR

Brief title
PAPA- study

Health condition

Approximately 15-20 % of all clinically recognized pregnancies in women of reproductive age will end in a
miscarriage. A possible complication of surgical treatment is intrauterine adhesion (IUA) formation or Asherman
syndrome. IUA can be asymptomatic but often results in symptoms. Recurrent curettage, defined as one or more
curettage in history, is a risk factor for IUA formation. Application of hyaluronic acid, a physical barrier has shown to be effective in prevention or reduction of adhesion formation in the uterine cavity. In the present protocol we propose to study whether intrauterine application of hyaloronic acid in patients undergoing a recurrent curettage because of a miscarriage could prevent or reduce the formation of intra-uterine adhesions.

Sponsors and support

Primary sponsor: Sint Lucas Andreas ziekenhuis
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek Gynaecologenmaatschap Amsterdam West, SWOGA.

Intervention

Outcome measures

Primary outcome

The primary outcome measure is number of patients with intra-uterine adhesions during the follow-up hysteroscopy.

Secondary outcome

1. Severity of intra-uterine adhedsions (IUAs);

2. Time to conceive during one year;

3. Number and time to clinical pregnancy during one year;

4. Number and time to ongoing pregnancy during one year;

5. Number of miscarriages during the first year after curettage.

Study description

Background summary

Women with a miscarriage undergoing a recurrent curettage have an increased risk for adhesions formation. Adhesion formation is related with menstrual disturbances, fertility disorders and if pregnancy occurs it may be complicated. Prevention of adhesion formation is essential because of the possible serious implications. Application of hyaluronic acid has shown to prevent adhesion formation in the uterine cavity.
The hysteroscopic control offers the possibility to assess the presence of adhesions and the option to perform immediate adhesiolysis. Both are independent of the study arm and may therefore be beneficial to every patient included in the study.

Applications of hyaluronic acid has shown to be a safe procedure; no potential risk has been

reported since it’s introduction. Potential risks of curettage are bleeding, perforation of the uterus wall, infection and induction of intra-uterine adhesions.

Additional, patients are asked to fill in questionnaires (approximately 15 questions) 3, 6 months and one year after the procedure.

Study objective

In the present proposal we aim to study whether the intrauterine application of hyaloronic acid (Hyalobarrier ® Gel Endo) immediately after curettage, in patients with a recurrent curettage reduces the incidence and severity (ESGE score/classification) of intra-uterine adhesions.

Study design

01-11-2011: Start recruiting patients;

01-06-2013: Finishing study.

Intervention

Patients will be randomised and allocated to curettage with adhesion prevention (hyaloronic) group or curettage alone (control) group. Hyaloronic acid will be applied intrauterine once, immediately after curettage. A hysteroscopy is planned 8-12 weeks after the initial operation for identification of the adhesions and their extent in all patients.

Contacts

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Eligibility criteria

Inclusion criteria

Consented patients, who had at least one previous suction or abrasive (blunt or sharp) curettage for a miscarriage in the history, visiting the outpatient clinic with a miscarriage and planned for curettage, will be included in the study. The ultrasound is a key in the diagnosis of miscarriage; at least one recent ultrasound examination (made within 7 days before randomisation) is required for inclusion. The maximum gestational age at inclusion is 14 weeks.

Exclusion criteria

1. Patients with a suspected mola pregnancy;

2. Patients with a previous hysteroscopic surgery (endometrial ablation, removal of fibroids or surgical correction of congenital uterine anomalies);

3. Patients with contra-indications for one of the procedures at the time of randomisation;

4. Patients who do not master the Dutch or English language;

5. Patients who are younger than 18 years of age or mentally incompetent;

6. Patients with severe signs of infection (sepsis).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2011
Enrollment:	150
Type:	Anticipated

Ethics review

Positive opinion

Date:	27-10-2011
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	NL2973
NTR-old	NTR3120
Other	METc VUmc : 2011/256
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A