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

Gepubliceerd: 27-10-2011 Laatst bijgewerkt: 18-08-2022

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/…

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

Samenvatting

ID

NL-OMON22431

Bron
NTR

Verkorte titel
PAPA- study

Aandoening

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.

Ondersteuning

Primaire sponsor: Sint Lucas Andreas ziekenhuis
Overige ondersteuning: Stichting Wetenschappelijk Onderzoek Gynaecologenmaatschap Amsterdam West, SWOGA.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

01-11-2011: Start recruiting patients;

01-06-2013: Finishing study.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-11-2011
Aantal proefpersonen:	150
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	27-10-2011
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	NL2973
NTR-old	NTR3120
Ander register	METc VUmc : 2011/256
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A