Post Abortion Prevention of Adhesions. Evaluation of hyaluronic acid (hyalobarier ® Gel Endo) .

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The goal of the study is to determine if the use of Hyalobarrier® Endo prevents or reduces the chance of adhesions. We also would like to know how many woman become pregnant within the year and how the pregnancy goes.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Uterine, pelvic and broad ligament disorders
Study type	Interventional

Summary

ID

NL-OMON39230

Source
ToetsingOnline

Brief title
PAPA

Condition

- Uterine, pelvic and broad ligament disorders

Synonym
adhesions

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: SWOGA; Stichting Wetenschappelijk Onderzoek Gynaecologenmaatschap Amsterdam West

Intervention

Keyword: abortion, adhesion, curettage, hyalobarier ® Gel Endo

Outcome measures

Primary outcome

Presence and extent of adhesions in patients after recurrent curettage,

evaluated by hysteroscopy 8-12 weeks after the initial procedure, using the

ESGE classification.

Secondary outcome

Hazzard ratio for an ongoing pregnancy (in those patients willingly to

conceive) after one year follow-up. Pregnancy and miscarriage rate one year

after the procedure, complication during the procedure, any side-effect, number

of performed re-interventions during one year.

Study description

Background summary

A rare occuring complication with curettage is the development of intra-uterine adhesions; the syndrome of Asherman. In serious cases the menstual blood cannot go out as a result of the adhesions. Fertility problems can also occur, because no implantation can occur. Recent research shows that women that undergo more than one curettage have a higher risk in forming adhesions. Because of the detrimental effects of the adhesions it is important to prevent this.

Study objective

The goal of the study is to determine if the use of Hyalobarrier® Endo prevents or reduces the chance of adhesions. We also would like to know how many woman become pregnant within the year and how the pregnancy goes.

Study design

If a patient takes part in this study she will be randomised in one of the two

groups:

A curretage will be done:
1. In the uterus Hyalobarrier® Endo will be placed
OR
2. No agent will be inserted.

Intervention

In half of all subjects after the curettage the agent in the uterus Hyalobarrier® Endo will be placed

Study burden and risks

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 and 12 months after the procedure.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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 or termination of pregnancy 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

- Patients with a suspected mola pregnancy.
- Patients with a previous hysteroscopic surgery (endometrial ablation, removal of fibroids or surgical correction of congenital uterine anomalies)
- Patients with contraindications for one of the procedures at the time of randomisation
- Patients who do not master the Dutch or English language.
- Patients who are younger than 18 years of age or mentally incompetent.
- Patients with severe signs of infection (sepsis).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Primary purpose: Prevention

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	16-12-2011
Enrollment:	150
Type:	Actual

Medical products/devices used

Generic name:	hyalobarier ® Gel Endo
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	14-12-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-03-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-05-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-11-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-01-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-12-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL35693.029.11