Evaluation of endometrium stimulation with estrogen gestagen post hysteroscopic adhesiolysis and long term outcomes

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24510

Source
Nationaal Trial Register

Brief title
SEPA

Health condition

Asherman Syndrome

Sponsors and support

Primary sponsor: No sponsor
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Spontaneous recurrence of intra uterine adhesion

Secondary outcome

• Ongoing pregnancy (in those patients willingly to conceive) after one year follow-up. During a follow up of 1 year the number and time to conceive will be recorded. The clinical as well as the ongoing pregnancies (defined as intra-uterine heart activity at 12 weeks gestation)

• The number of performed re-interventions (hysteroscopic adhesiolysis in the OR or outpatient clinic or adhesiolysis without hysteroscopy (dilatation) in outpatient clinic setting)

• Complication related to postoperative estrogen and gestagen administration or any side-effect.

. Long term follow-up over 10 years, re-interventions, fertility outcome, pregnancy outcome, obstetrical outcome and chronicle pelvic pain

Study description

Background summary

Evaluation of exogenous hormone administration (oral administration of estrogen and gestagen) starting immediately after successful hysteroscopic adhesiolysis, in patients with Asherman Syndrome (As) reduces or prevents the incidence and severity (ESGE score/classification) of spontaneous re-adhesions better then the endogen production of hormones. Secondly to evaluate the long term outcome of fertility, pregnancy and obstetrical outcome and chronical pelvic pain

Study objective

The hypothesis is that exogenous hormone administration (oral administration of estrogen and gestagen) starting immediately after successful hysteroscopic adhesiolysis, in patients with Asherman Syndrome reduces or prevents the incidence and severity (ESGE score/classification) of spontaneous recurrence of adhesion better then the endogen production of hormones.

Study design

1 year, 3 years, 10 years

Intervention

exogenous hormone administration (oral administration of estrogen and gestagen) starting immediately after successful hysteroscopic adhesiolysis

Contacts

Public
Spaarne Gasthuis
Miriam Hanstede

0624600426
Scientific
Spaarne Gasthuis
Miriam Hanstede

0624600426

Eligibility criteria

Inclusion criteria

Consented patients with Asherman Syndrome (AS) who had a successful hysteroscopic adhesiolysis, defined as a restore of the normal uterine cavity, were eligible for inclusion. Patients with AS should be defined as patients with any diminishing of blood flow (secondary amenorrhoea or secondary hypomenorrhoe) after trauma to the uterine cavity due to pregnancy related surgical procedure with the presence of intrauterine adhesions with a previous history of normal menstrual blood flow.

Exclusion criteria

- Patients with a suspected AS due to tuberculosis or schitsosomiasis.
- Patients with an uncorrected anovulation, amenorrhoe or oligomenorrhoe previous to the AS
- Patients with suspected AS due to hysteroscopic surgery with the use of electrocoagulation (used in fibroid or polyp surgery)
- Patients with congenital uterine anomalies
- Patients with contraindications for a surgical adhesiolysis
- Patients who do not master the Dutch or English language.
- Patients who are younger than 18 years of age or mentally incompetent.
- Patients with contraindications for estrogen and or gestagen
-Patients who use hormonal suppletion

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2013
Enrollment:	110
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	09-08-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45234
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9655
CCMO	NL41190.094.13
OMON	NL-OMON45234

Study results