

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

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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...

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

Samenvatting

ID

NL-OMON24510

Bron

Nationaal Trial Register

Verkorte titel

SEPA

Aandoening

Asherman Syndrome

Ondersteuning

Primaire sponsor: No sponsor

Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Spontaneous recurrence of intra uterine adhesion

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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.

Onderzoeksopzet

1 year, 3 years, 10 years

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Spaarne Gasthuis
Miriam Hanstede

Wetenschappelijk

Spaarne Gasthuis
Miriam Hanstede

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Patients with a suspected AS due to tuberculosis or schistosomiasis.
- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2013
Aantal proefpersonen:	110
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	09-08-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45234
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten