Essure® intratubal device placement for Hydrosalpinx in patients undrgoing IVF treatment. A randomized comparison with laparoscopic removal of the hydrosalpinx.

Gepubliceerd: 21-10-2009 Laatst bijgewerkt: 18-08-2022

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

Samenvatting

ID

NL-OMON24394

Bron
NTR

Verkorte titel
Dutch Essure® versus Salpingectomy for Hydrosalpinx

Aandoening

Hydrosalpinx, IVF, Essure, Laparoscopy, salpingectomy

Ondersteuning

Primaire sponsor: VUmc, afdeling Voortplantingsgeneeskunde.
Overige ondersteuning: VUmc, afdeling Voortplantingsgeneeskunde.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Clinical pregnancy rate (defined by the demonstration of fetal heart activity on ultrasound).

Toelichting onderzoek

Achtergrond van het onderzoek

The primary objective is to evaluate and compare the impact of hysteroscopic Essure® intratubal device placement (new treatment) and laparoscopic salpingectomy (standard treatment) on IVF-ET outcomes of patients with hydrosalpinx.

Laparoscopic salpingectomy for hydrosalpinx may compromise ovarian reserve in women undergoing IVF-ET by partly disrupting the blood flow to the ovary. Therefore, our secondary objective is to evaluate ovarian reserve through measurements of early follicular phase serum FSH & AMH levels as well as antral follicle counts (transvaginal ultrasound) presurgery and 3 months postsurgery in both study groups.

Doel van het onderzoek

The hypothesis of this study is that hysteroscopic treatment of hydrosalpinges with essure devices is as effective as laparoscopic salpingectomy with respect to subsequent IVF-ET outcomes but is related to less burden (in contrast to laparoscopic treatment, hysteroscopic treatment can be performed in an outpatient setting, without use of general anaesthesia, with shorter procedure times and a quicker recovery) and possibly also less interventional and/or anaesthesiologic risk for the patient.

Onderzoeksopzet

1. Baseline;

2. 3 months;

3. After first IVF.

Onderzoeksproduct en/of interventie

Essure® intratubal device placement (new treatment) and laparoscopic salpingectomy (standard treatment) on IVF-ET outcomes of patients with hydrosalpinx.

Contactpersonen

Publiek

V. Mijatovic
Amsterdam
The Netherlands
+31 (0)20 4440070

Wetenschappelijk

V. Mijatovic
Amsterdam
The Netherlands
+31 (0)20 4440070

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Presence of uni- or bilateral hydrosalpinges prior to IVF-ET. A hydrosalpinx is defined as: a distally occluded fallopian tube which was pathologically dilated or became pathologically dilated when patency was tested by hysterosalpingography and/or laparoscopy. The hydrosalpinx should be visible on ultrasound performed midcyclically as these have been associated with the poorest prognosis regarding IVF-ET outcomes [5];

2. Female age ¡Ü 40 years at the time of randomization;

3. Patient suitable for IVF-ET treatment;

4. Patient suitable for laparoscopic surgery;

5. Concomitant male factor requiring intracytoplasmatic sperm injection (ICSI) is accepted provided that a centre has an established ICSI programme with results equivalent to conventional IVF.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Female age > 40 years at the time of randomization;

2. Pregnancy or suspected pregnancy;

3. Recent or active pelvic infection;

4. Previous tubal ligation;

5. Evidence of proximal tubal occlusion in the hydrosalpinx seen at HSG or at laparoscopy;

6. Patient not suitable for IVF-ET;

7. Patient not suitable for laparoscopic surgery;

8. Concomitant male factor not suitable for ICSI;

9. Uterine fibroids interfering with IVF-ET, ICSI or placement of Essure ® devices;

10. Presence of any malignancy.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	24-09-2009
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	21-10-2009
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	NL1955
NTR-old	NTR2073
Ander register	METC Vumc Amsterdam : 2008-337
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A