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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24394

Source
NTR

Brief title
Dutch Essure® versus Salpingectomy for Hydrosalpinx

Health condition

Hydrosalpinx, IVF, Essure, Laparoscopy, salpingectomy

Sponsors and support

Primary sponsor: VUmc, afdeling Voortplantingsgeneeskunde.
Source(s) of monetary or material Support: VUmc, afdeling Voortplantingsgeneeskunde.

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Success rate of proximal tubal occlusion with Essure® devices (demonstrated by HSG);

2. Miscarriage rate;

3. Implantation rate (defined as number of gestational sacs on ultrasound/ number of embryo¡¯s transferred);

4. Ectopic pregnancy rate;

5. Multiple pregnancy rate;

6. Complications rate;

7. Ovarian reserve pre- vs. postsurgery (determined by early follicular serum FSH/AMH as well as antral follicle counts).

Study description

Background summary

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.

Study objective

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.

Study design

1. Baseline;

2. 3 months;

3. After first IVF.

Intervention

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

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	24-09-2009
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion Date:	21-10-2009
Application type:	First submission

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
NTR-new	NL1955
NTR-old	NTR2073
Other	METC Vumc Amsterdam : 2008-337
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A