Prospective randomized trial to evaluate and to compare the impact of hysteroscopic Essure® intratubal device placement and laparoscopic salpingectomy on IVF-ET outcomes of patients with hydrosalpinx.

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1. To evaluate and compare the impact of hysteroscopic Essure® intratubal device placement and laparoscopic salpingectomy on IVF-ET outcomes of patients with hydrosalpinx.2. It is still uncertain whether laparoscopic salpingectomy for hydrosalpinx...

Ethical review	Approved WMO
Status	Completed
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Interventional

Summary

ID

NL-OMON39635

Source
ToetsingOnline

Brief title
The DESH (Dutch Essure® versus Salpingectomy for Hydrosalpinx) Trial.

Condition

- Pregnancy, labour, delivery and postpartum conditions
- Ovarian and fallopian tube disorders
- Obstetric and gynaecological therapeutic procedures

Synonym
Blocked fallopian tube filled with fluid

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Conceptus Inc., Moutain View, California, USA,Stichting Wetenschappelijk Onderzoek Gynaecologie (SWOG)

Intervention

Keyword: Essure, Hydrosalpinx, IVF, Salpingectomy

Outcome measures

Primary outcome

• Live birth rate

• Clinical pregnancy rate (defined by the demonstration of fetal heart activity

on ultrasound).

• Success rate of proximal tubal occlusion with Essure® devices (demonstrated

by HSG)

Secondary outcome

• Miscarriage rate

• Implantation rate (defined as number of gestational sacs on ultrasound/

number of embryo*s transferred)

• Ectopic pregnancy rate

• Multiple pregnancy rate

• Complications rate

• Ovarian reserve pre- vs. postsurgery (determined by early follicular serum

FSH/AMH as well as antral follicle counts)

• Change in endometrial receptivity, determined by

endometrial biopsy once before treastment of the hydrosalpinx and the second 12

weeks post treatment. Endometrial receptivity will be

examined by measuring the gene expression in the biopsies and by

histological dating of the biopsies.

Study description

Background summary

Subfertile patients with hydrosalpinges have been identified as a subgroup with significantly poorer outcomes of IVF-ET compared to patients without hydrosalpinx. Especially patients with hydrosalpinges large enough to be visible on ultrasound are associated with the the poorest prognosis. The theories explaining the harmful effect of hydrosalpinges on IVF-ET outcomes are multiple and include the following: 1. a mechanical washout of the transferred embryos through tubo-uterine reflux of hydrosalpinx fluid, 2. a direct embryotoxic effect of the hydrosalpinx fluid 3. a lower endometrial receptivity as an effect of disturbed expression of the cytokine and integrin system by the presence of a hydrosalpinx, thus impairing the implantation potential. In the line of these theories, any surgical intervention interrupting the communication between hydrosalpinx and uterine cavity would stop the leakage of hydrosalpinx fluid and improve the endometrial environment for implantation. Laparoscopic salpingectomy is currently considered the standard treatment for hydrosalpinx prior to IVF-ET. This is based on a Cochrane systematic review showing increased odds of ongoing pregnancy and live birth (OR 2.13, 95% CI 1.24-3.65) with laparoscopic salpingectomy for hydrosalpinges prior to IVF-ET. Laparoscopic salpingectomy prior to IVF-ET in patients with hydrosalpinges restores IVF outcomes but carries also all the risks associated with operative intervention and general anaesthesia. Hysteroscopic treatment with essure devices may form an attractive alternative to laparoscopic treatment of hydrosalpinx. In contrast to the laparoscopic salpingectomy, the essure treatment can be performed in an outpatient setting, without use of general anaesthesia, with shorter procedure times and a quicker recovery time.
Our hypothesis is that hysteroscopic treatment of hydrosalpinges with essure devices is as effective as laparoscopic salpingectomy with respect to subsequent IVF-ET outcomes but with less burden and possibly also less interventional risk for the patient.

Study objective

1. To evaluate and compare the impact of hysteroscopic Essure® intratubal

device placement and laparoscopic salpingectomy on IVF-ET outcomes of patients with hydrosalpinx.

2. It is still uncertain whether laparoscopic salpingectomy for hydrosalpinx may compromise ovarian reserve in women undergoing IVF-ET by partly disrupting the blood flow to the ovary. In order to evaluate this possible side-effect of salpingectomy, early follicular phase serum FSH & AMH levels as well as antral follicle counts will be determined presurgery and 3 months postsurgery in both the Essure® and the salpingectomy groups.

Study design

a multi-centre, prospective, open label, randomized trial.

Intervention

Laparoscopic salpinectomy versus Hysteroscopic placement of essure devices.

Study burden and risks

The available data in the literature show very promising results regarding the effectiveness and safety of hysteroscopic treatment using Essure devices for hydrosalpinges prior to IVF. In comparison to laparoscopic salpingectomy, the hysteroscopic treatment can be done in an outpatient setting without general anesthesia and with a quicker recovery time which is associated with less burden for patients.
In this trial, 3 visits are included. During visit 1 the patient will undergo an physical/gynaecological examination, a transvaginal ultrasound scan, an endometrial biopsy as well as a bloodinvestigation (15 mL). During visit 2 one of the two asigned treatments (hysteroscopic placement of Essure devices versus laparoscopic salpingectomy) will be performed. During visit 3 a bloodinvestigation, a transvaginal ultrasound scan, an endomtrial biopsy and a hysterosalingography (only for patients who underwent and Essure treatment) will be performed.

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

- Presence of uni- or bilateral hydrosalpinges (established with transvaginal ultrasouns)
- Female age <= 40 years at the time of randomization
- Patient suitable for IVF-ET treatment
- Patient suitable for laparoscopic surgery

Exclusion criteria

- Female age > 40 years at the time of randomization
- Pregnancy or suspected pregnancy
- Recent or active pelvic infection
- Evidence of proximal tubal occlusion in the hydrosalpinx seen at HSG or at laparoscopy
- Patient not suitable for IVF-ET
- Patient not suitable for laparoscopic surgery

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	01-09-2009
Enrollment:	80
Type:	Actual

Medical products/devices used

Generic name:	Essure intratubal device
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	21-08-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-05-2014
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	NL25640.029.08