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Hysterosalpingo-foam sonography as an Essure confirmation test

Submission date	Recruitment status	[_] Prospectively registered
09/04/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/07/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/01/2019	Pregnancy and Childbirth	

Plain English summary of protocol

Background and study aims

Essure is a permanent birth control method for women. Implantation of Essure does not require a surgical incision. In the procedure, Essure micro-inserts are inserted through the vagina and cervix and into the fallopian tubes. Over a period of three months, tissue forms around the micro-inserts, which blocks the fallopian tubes and creates a barrier that keeps sperm from reaching the eggs, thus preventing conception. Women need to use additional birth control in the first three months following the procedure, after which micro-insert position or fallopian tube occlusion (blocking) should be checked by a confirmation test. Confirmation tests currently vary from country to country. In Slovenia, vaginal ultrasound (US) is performed three months after the procedure to assess the micro-insert position, which is defined as correct, indeterminate or incorrect. In cases with indeterminate or incorrect micro-insert position, a tubal patency test is performed. Hysterosalpingography (HSG) has been the gold standard for such confirmation: a radiographic contrast material is injected into the womb to detect the closure of the fallopian tubes by X-ray. Because of the potential adverse effect of HSG, alternative methods have been suggested to verify the position of the micro-inserts or the tubal occlusion. Ultrasound assessment, however, is the least invasive method of all. The use of ultrasound with contrast material – hysterosalpingo-contrast sonography (HyCoSy), has been used for checking the patency of the fallopian tube in the past, but this contrast material is no longer available for gynaecological use. Recently, ExEm foam was introduced as a contrast medium for contrast sonography – hysterosalpingo-foam sonography (HyFoSy), which is a safe and a successful procedure to demonstrate tubal patency as a first step procedure in patients with troubles in conceiving a child (subfertility). In this study, the US, HSG and HyFoSy findings in patients after Essure sterilization are compared. How US findings correlate with tubal blockage on HSG are compared. This study also investigates if HyFoSy, which is a less invasive procedure than HSG, is as successful as HSG in determinating the tubal blockage. The study's findings could change the confirmation test protocol for women after Essure sterilization.

Who can participate?

Women aged 35 to 50 years old that are undergoing Essure hysteroscopic sterilization for pregnancy prevention at University Medical Centre Maribor, Slovenia.

What does the study involve?
Essure hysteroscopic sterilization is performed, by which Essure micro-inserts are put into the fallopian tubes through the vagina and cervix. Twelve weeks after the procedure all patients have three confirmation tests, where micro-insert position and tubal occlusion are assessed. US is performed to assess the micro-insert position. Then both HyFoSy and HSG are performed to assess tubal patency. At HyFoSy, tubal patency is tested with the use of vaginal ultrasound by injecting ExEm foam into the womb though vagina. At HSG, tubal patency is tested by X-ray by injecting Iopamiro radiographic contrast medium into the womb through vagina. Questionnaires are filled in by the patients and the researchers. At the end of the study, the researchers compare how US findings correlate with tubal blockage on HSG and if HyFoSy is as successful as HSG in confirming the tubal blockage.

What are the possible benefits and risks of participating?
There will be no immediate direct benefit to those taking part. But there should be benefits to future patients referred to the Essure hysteroscopic sterilization because the results of the study may have an influence on the confirmation test protocol after Essure sterilization. Side effects of the Essure procedure are rare, but include incorrect placement of micro-inserts and perforation of the womb or the fallopian tube. In these instances, surgery may be needed to repair the damage of the tissue. Some women experience nausea, vomiting or fainting. Pain, cramping, vaginal bleeding, and pelvic or back discomfort can be present for a few days after the procedure. In very rare instances, an Essure micro-insert may be expelled from the body. Long term side effects of the Essure procedure include chronic pelvic pain and migration of the micro-insert into the lower abdomen and pelvis. If this happens, it may be necessary to surgically remove the micro-insert. No birth control method is 100% effective. There is a very small chance that women become pregnant after completing the Essure procedure, and if so, they are more likely to have a pregnancy outside the womb (ectopic pregnancy). The Essure micro-insert is made of materials that include a nickel-titanium alloy. Patients who are allergic to nickel may have an allergic reaction to the inserts. Symptoms include rash, itching and hives. There are no risks during US examination. Because HSG requires an X-ray, women are exposed to very low levels of radiation. Other risks of HSG are similar to the risks of HyFoSy. They are rare and include allergy, pain, fainting, spotting and infection.

Where is the study run from?
University Medical Centre Maribor, Slovenia.

When is study starting and how long is it expected to run for?
January 2013 to June 2016

Who is the main contact?
Maja Rosic, MD

Contact information

Type(s)
Scientific

Contact name
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Contact details

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Additional identifiers

Protocol serial number
IRP-2013/01-06

Study information

Scientific Title
Hysterosalpingo-Foam Sonography vs. HysteroSalpinGography as an Essure hysteroscopic sterilization confirmation test

Acronym
HyFoSy vs. HSG

Study objectives
Hysterosalpingo-foam sonography is equivalent to hysterosalpingography in evaluation of Fallopian tube patency after Essure hystroscopic sterilization.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Republic of Slovenia National Medical Ethics Committee, 21/08/2012, ref: 114/08/12

Study design
Single-centre interventional study

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Essure hysteroscopic sterilization

Interventions
Essure hysteroscopic sterilization is performed in an outpatient setting. One hour before the procedure, patient takes premedication with diazepam 5 mg orally and ketoprofen 100 mg rectally.
At the procedure, Essure micro-inserts are inserted into the proximal parts of Fallopian tubes at the time of hysteroscopy. Questionnaire is filled in by the hysteroscopist.
12 weeks after the procedure all patients have 3 confirmation tests, which are performed in

order to evaluate micro-insert location or tubal occlusion. At that time, questionnaire is filled in by the patient. Transvaginal 2D ultrasound is performed to assess the micro-insert position. Then both hysterosalpingo-foam sonography (HyFoSy) and hysterosalpingography (HSG) are performed to assess tubal patency. At HyFoSy, 20 ml of ExEm foam is infused through the cervix into uterine cavity by ExEm Foam Kit catheter. Tubal patency is evaluated by transvaginal ultrasound. At HSG, 20 ml of Iopamiro 370 radiographic contrast medium is installed into uterine cavity by transcervical HSG catheter. Tubal patency is evaluated by X-ray. Questionaires are filled in by the researchers for all 3 confirmaton tests.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Comparison of Fallopian tubes patency performed with both hysterosalpingo-foam sonography (HyFoSy) and hysterosalpingography (HSG) 3 months after Essure hysteroscopic sterilization.

Key secondary outcome(s))
1. Efficacy of Essure hysteroscopic sterilization, determined by hysterosalpingography 3 months after Essure hysteroscopic sterilization
2. Complications of Essure hysteroscopic sterilization, determined by hysteroscopist at the time of Essure hysteroscopic sterilization and by the patient at the 3 months follow up visit
3. Pain at Essure hysteroscopic sterilization, measured using the visual analogue score (VAS) at the time of the procedure
4. Patient satisfaction with Essure hysteroscopic sterilisation, measured by visual analogue score (VAS) 3 months after the procedure
5. Pain at hysterosalpingo-foam sonography (HyFoSy) and at hysterosalpingography (HSG), measured by visual analogue score (VAS) at the time of the procedures
6. Determine, how transvaginal ultrasound (US) assessment of Essure micro-insert position corresponds with tubal patency, determined by US and hysterosalpingography (HSG) 3 months after Essure hysteroscopic sterilization

Completion date
30/06/2016

Eligibility

Key inclusion criteria
Patients undergone Essure hysteroscopic sterilization for pregnancy prevention.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Patients who decline transvaginal ultrasound examination
2. Patients who decline hysterosalpingo-foam sonography examination
3. Patients who decline hysterosalpingography
4. Patients who decline to fill in a questionnaire
5. Patients who wish to be excluded from the study

Date of first enrolment
24/01/2013

Date of final enrolment
30/06/2016

Locations

Countries of recruitment
Slovenia

Study participating centre
University Medical Centre Maribor
Ljubljanska 5
Maribor
Slovenia
2000

Sponsor information

Organisation
University Medical Centre Maribor

ROR
https://ror.org/02rjj7s91

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Medical Centre Maribor, Slovenia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2018	29/01/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes