Pivotal Study for Safety & Efficacy of AltaSeal® A Hysteroscopically Placed Mechanical Occlusion Implant for Hysteroscopic Sterilisation

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The primary objective of this clinical trial is to evaluate the safety and effectiveness of the AltaSeal® implants in providing bilateral mechanical occlusion of the fallopian tubes and in preventing pregnancy.Additional objectives are as follows:*...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Obstetric and gynaecological therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON41001

Source
ToetsingOnline

Brief title
CIP-TOI-006

Condition

- Obstetric and gynaecological therapeutic procedures

Synonym
Occlusion of the fallopian tubes, sterilization with the aid of hysteroscopy

Research involving
Human

Sponsors and support

Primary sponsor: AltaScience Ltd.

Source(s) of monetary or material Support: AltaScience Ltd.

Intervention

Keyword: Fallopian tubes, Hysteroscopy, Sterilization, tubal, Tubal occlusion

Outcome measures

Primary outcome

Primary Endpoints:

Safety is assessed by measuring major complication rates/serious adverse event rates associated with the use of the AltaSeal® device.

Efficacy is assessed by measuring the number of confirmed pregnancies at 1 year among patients told to rely on AltaSeal® for contraception.

Secondary outcome

Secondary Endpoints:

The secondary endpoints of this Pivotal Study are minor complications, reliance rate and patient satisfaction and comfort with placement procedure and device wearing.

The overall aim of the AltaSeal® device in this study is to achieve bilateral occlusion of the fallopian tubes in a manner that is tolerable and safe to the patient. The primary safety and efficacy endpoints will be the principal indicators of success.

Study description

Background summary

Fallopian Tube Sterilisation has been performed for many years using either the transabdominal or transvaginal/transcervical (hysteroscopic) route. Fallopian Tube Sterilisation involves disrupting the fallopian tube to ensure that sperm cannot get access to the egg and therefore allow fertilisation (Figure 4). Blocking the tubes can be achieved by tying, cutting, sealing, application of clamps, clips or rings, or removing a section of the fallopian tube. Currently, tubal ligation requires an abdominal incision and is carried out under a general or local anaesthetic.

Hysteroscopic sterilisation involves accessing the fallopian tube in a non-invasive fashion via the uterine cervix, using a hysteroscope. Hysteroscopic sterilisation has moved female sterilization from a minimally invasive laparoscopic technique, which requires entry into the abdominal cavity, to a less invasive hysteroscopic procedure. Along with the decreased potential for complications, its ease of performance with minimal anaesthesia has facilitated a move from the operating room to the doctor*s office.
The benefits of hysteroscopic sterilisation include:

* Less invasive * no surgery is required and therefore no laparoscopic risks or skin incisions.
* Beneficial for patients contraindicated for general anaesthetic such as obese patients.
* Office-based procedure.
* Rapid recovery time.
* Reduced costs for hospital and patients.
* No surgical incisions required, therefore:
o No risk of bowel injury through adhesions such as patients with previous surgery or inflammatory bowel disease.
o Less risk of bleeding complications in case of clotting disorders or anti-coagulant medication
* Risks associated with hormone-based contraceptives eliminated.

While the possibility of carrying out fallopian tube sterilisation with a hysteroscope had been considered for many years the first product to receive FDA approval was the Essure® device from Bayer (Conceptus Inc.). The Essure® implant is made from a 316LVM stainless steel coil, a nickel-titanium coil and polyethylene terephthalate (PET) fibres. The Essure® implant is placed hysteroscopically and its mechanism of action is the occlusion over many months as a result of tissue fibrosis around and through the implant to occlude the fallopian tube. The Essure® device requires the patient to wait a minimum of three months to ensure tissue fibrosis enables fallopian tube occlusion. The patient must then return after three months for a confirmatory HSG (X-ray) to confirm fallopian tube occlusion.

AltaScience believes that the AltaSeal® device will have the following potential clinical advantages over the Essure® hysteroscopically placed tubal occlusion implant:

* Mechanical occlusion resulting in permanent sterilisation.
* Easy to place.
* Minimal user training.
* The AltaSeal® implant is shorter than Essure® and is placed within the fallopian tube, therefore AltaSeal® will not protrude into the uterine cavity as Essure® does.
* No intra-abdominal fibrotic reaction (PET fibres in Essure® device can cause fibrotic reaction in case of unintended perforation).
* AltaSeal® is made from 316LVM Stainless Steel * no risk of nickel metal allergy.

Study objective

The primary objective of this clinical trial is to evaluate the safety and effectiveness of the AltaSeal® implants in providing bilateral mechanical occlusion of the fallopian tubes and in preventing pregnancy.

Additional objectives are as follows:
* To determine the ease of inserting the device into the fallopian tube (investigator feedback);
* To determine the ease of achieving correct placement of the device in the intramural section of the fallopian tube;
* To determine non-migration of the implant by TV/TA ultrasound;
* To measure the average implantation procedure time;
* To evaluate patient comfort before and after procedure.

Study design

This study is a multicentre, non-randomised, single arm study of patients seeking permanent contraception.
This study is designed to evaluate the safety and efficacy of the AltaSeal® device. During the study 214 patients will be recruited. The study design is set out to investigate each of the stated objectives above and minimise potential bias. In order to do this, it is intended that after screening has taken place, 214 patients shall partake in the study and shall receive two AltaSeal® devices (1 in each fallopian tube). If the patient meets the requirements of the clinical investigation (inclusion/exclusion criteria), they shall be invited to participate, give consent and shall subsequently be assigned a patient number.

Intervention

Hysteroscopic sterilization by mechanical bilateral occlusion of the fallopian tubes.

Study burden and risks

RISKS
The risks and possible side effects associated with the implant placement procedure are as follows:
* Pregnancy.
* Abdominal/pelvic pain, cramping and vaginal bleeding may occur during and/or after implant placement. This is usually mild and treated with paracetamol.
* Nausea or vomiting may occur during and/or directly after placement. This is expected to be transient and successfully treated with medication.
* Fainting or vasovagal response.
* Perforation or dissection of the fallopian tube or uterus with possible injury to the bowel, bladder and major blood vessels.
* Incorrect placement of the implant that cannot be relied upon for contraception and that may result in post-operative pain and require surgical removal.
* Placement not possible in either fallopian tube.
* Excessive absorption of distension media.
* Infection causing damage to uterus, fallopian tubes or pelvic cavity.
* Implant expulsion (movement into the uterine cavity or out of the body) or migration (movement to the distal fallopian tube or out of the fallopian tube into the peritoneal cavity).
* Further risks associated with follow-up procedures.

The risks and possible side effects associated with potential future procedures are as follows :
* Unknown risks associated with electrocautery procedures. It is recommended that electrocautery be avoided in surgical procedures undertaken on the uterine cornua and fallopian tubes.
* Any intrauterine procedure could interrupt the implants and adversely affect the ability of the implants to prevent pregnancy.
* There is the potential that unknown risks exist.

BENEFITS
The direct benefit to the patient for participating in this study is the opportunity to select a simple and minimally invasive method of permanent contraception that can be carried out within a short procedure time.

Additional potential benefits to the patient when compared to alternative methods of hysteroscopic sterilisation are as follows:

* The ability to achieve permanent contraception using small implants made solely from the widely used medical grade metal, 316LVM stainless steel.
* An implant that is easy to place and deploy, is relatively safe and potentially immediately effective.

Additional potential benefits to the patient when compared to existing methods of sterilisation and contraception are as follows:

* Less invasive * no surgery is required and therefore no laparoscopic risks or skin incisions.
* Beneficial for patients contraindicated for general anaesthetic such as obese patients.
* Office-based procedure.
* Rapid recovery time.
* Reduced costs for hospital and patients.
* No surgical incisions required.
* Risks associated with hormone-based contraceptives eliminated.

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

Patients aged 18 to 44 years.

Body weight within range of 40-136kg.
Patients who are seeking permanent contraception.
Patients who have at least one live birth.
Patients who are willing to participate in the clinical study and are able to provide written informed consent prior to study participation and agree to comply with all study specified requirements.
Willing to undergo a transvaginal and/or transabdominal ultrasound following insertion of the device.
Willing to use cover contraception post implantation.
Patients with a negative urinary hCG test.

Exclusion criteria

Patients uncertain about their desire to end fertility.
Patients in whom only one implant can be placed (including patients with apparent contralateral proximal tubal occlusion and patients with a suspected unicornuate uterus).
Patients who are pregnant or suspected pregnant.
Patients who have had a delivery or termination of a second trimester pregnancy less than 6 weeks before the AltaSeal® placement procedure.
Patients who have previously undergone a tubal ligation.
Patients with active or recent upper or lower pelvic infection.
Patients in whom both tubal ostia cannot be clearly identified .
Patients with a bifid uterus which inhibits implant placement.
Patients with a known allergy to any of the materials used in the device.
Patients with a known allergy to contrast media.
Patients undergoing immunosuppressive therapy are discouraged.
Patients who are incapable of giving their own consent.

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2014
Enrollment:	129
Type:	Actual

Medical products/devices used

Generic name:	AltaSeal®
Registration:	No

Ethics review

Approved WMO

Date:	31-07-2014
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL47804.015.14