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

Published: 14-02-2017
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The primary objective of this clinical trial is to evaluate the safety and effectiveness of the AltaSeal® implants to provide bilateral mechanical occlusion of the fallopian tubes resulting prevention of pregnancy.

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

Summary

ID

NL-OMON49253

Source
ToetsingOnline

Brief title
CIP-TOI-007_NL

Condition

- Obstetric and gynaecological therapeutic procedures

Synonym
Occlusion of the Fallopian Tubes, sterilization with 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 Occlusion

Outcome measures

Primary outcome

Primary Endpoints:

Efficacy:

* Pregnancy rate at 12 months.

* Reliance rate

Safety:

* Percentage of adverse events (minor & major) following the device placement procedure

* Percentage of adverse events (minor & major) following device wearing.

Secondary outcome

Secondary Endpoints

Efficacy:

* Successful bilateral placement rate

* Patient satisfaction with device placement procedure and wearing

* Data for the development of the clinical patient profile for appropriate use

of the AltaSeal device

Study description

Background summary

Background of the study:

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. 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:
* No risk of bowel injury through adhesions such as patients with previous surgery or inflammatory bowel disease.
* 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, 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

Study objective

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

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 180 patients will be recruited. The study design is set out to investigate each of the stated objectives above and minimise potential bias. See research protocol (Section 7, Biostatistical Analysis Plan) for details.

Intervention

Hysteroscopic sterilization by mechanical bilateral occlusion of the fallopian tubes.

Study burden and risks

Risks
The risks and possible adverse events associated with the implant placement procedure are as follows: Update risks
1) Pregnancy, ectopic pregnancy, and risks associated with the treatment for both.
2) Incorrect placement of the implant that cannot be relied upon for contraception and that may result in post-operative pain and require surgical removal.
3) Placement not possible in either fallopian tube.
4) 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).
5) Abdominal and/or pelvic pain, cramping and vaginal bleeding may occur both during and after implant placement. This should be mild and treated with paracetamol.
6) Nausea or vomiting may occur during and/or directly after placement. This is expected to be transient and successfully treated with medication.
7) Perforation or dissection of the fallopian tube or uterus with possible injury to the bowel, bladder and major blood vessels.
8) Migraines.
9) Irregular and/or heavier periods.
10) Back Pain.
11) Swelling around the groin region.
12) Infection causing damage to uterus, fallopian tubes or pelvic cavity.
13) Additional risks associated with follow-up procedures.
14) Fainting or vasovagal response.
15) Excessive absorption of distension media.
16) Vaginal bleeding, cramping and bloating from coming off hormonal contraception.
17) Unknown risks not yet identified.

Following the AltaSeal® procedure the risks and possible adverse events associated with potential future medical 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 which could disturb the implants and adversely affect the ability of the implants to prevent pregnancy.
* Risks not yet identified.

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 the alternative

method of hysteroscopic sterilisation include:
* The ability to achieve permanent contraception using small biocompatible implants manufactured from 316LVM stainless steel.
* An implant that is easy to place, to deploy, is relatively safe and potentially is 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

1) Patients aged 22 to 44 years.
2) Body weight within range of 40-180kg.
3) Patients who are seeking permanent contraception.
4) Patients who have at least one live birth.
5) Patients who are willing to participate in a clinical study and are able to provide written informed consent prior to study participation and agree to comply with all study specified requirements.
6) Willing to undergo a TV/TA ultrasound both immediately and at 12 weeks following implantation of the device.
7) Willing to use cover contraception for 3 months post implantation.
8) Patients with a negative urinary hCG test.

Exclusion criteria

1) Patients uncertain about their desire to end fertility.
2) Patients with only one fallopian tube.
3) Patients who are pregnant or suspected pregnant.
4) Patients who have had a delivery or termination of a second trimester pregnancy less than 6 weeks before the AltaSeal® placement procedure.
5) Patients who have previously undergone a tubal ligation or other permanent sterilisation methods e.g. Essure® device.
6) Patients with active or recent upper or lower pelvic infection.
7) Patients in whom both tubal ostia cannot be clearly identified .
8) Patients with a bifid uterus which inhibits implant placement.
9) Patients with a known allergy to any of the materials used in the device.
10) Patients with a known allergy to contrast media.
11) Patients undergoing immunosuppressive therapy.
12) Patients who, in the investigator*s opinion, are not suitable candidates for the device placement procedure due to inability to comply with the protocol requirements.
13) Patients who are incapable of giving their own consent.
14) Patients with a cervical or uterine malignancy or un-investigated irregular vaginal bleeding.
15) Patients who are unsuitable for general/local anaesthetic or the sedation to be used during the procedure.
16) Patients who have a history of severe cramping or abdominal/pelvic pain.

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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):	16-02-2018
Enrollment:	180
Type:	Actual

Medical products/devices used

Generic name:	AltaSeal Device
Registration:	No

Ethics review

Approved WMO Date:	14-02-2017
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	30-05-2017
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO	

Date:	08-08-2017
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	14-05-2019
Application type:	Amendment
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	NL60282.015.16