A Multi-Centre Clinical Study to Evaluate the Safety and Effectiveness of the ESS505® Device to Prevent Pregnancy in Women Who Are Seeking Permanent Contraception

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To Evaluate the Safety and Effectiveness of the Essure® ESS505 Device to Prevent Pregnancy in Women Who Are Seeking Permanent Contraception (*Study*)

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON39616

Source
ToetsingOnline

Brief title
ESS505-003 Study

Condition

- Other condition

Synonym
birth control, contraception

Health condition

Women ages range 21 to 44 years desiring permanent contraception

Research involving
Human

Sponsors and support

Primary sponsor: Bayer
Source(s) of monetary or material Support: Conceptus Inc.

Intervention

Keyword: Contraception, Device, Permanent

Outcome measures

Primary outcome

Primary Endpoint:

- Following successful device placement (as confirmed via transvaginal ultrasound (*TVU*) confirmation test) performed at initial placement (day 0), assess occurrence of confirmed pregnancy at three months among subjects relying solely on ESS505 for contraception.

Secondary outcome

Secondary Endpoints:

- Following successful device placement as confirmed via a TVU, assess occurrence of confirmed pregnancies at 12 months after device placement among subjects relying solely on ESS505 for contraception.
- Assess severity and frequency of reported adverse events related to the device placement procedure.
- Assess severity and frequency of adverse events reported among subjects in whom one or more ESS505 inserts are placed.

Study description

Background summary

Evaluate the safety and long*term (approximately one year) effectiveness of the Essure System for Permanent Birth Control ESS505 device in preventing pregnancy.

Study objective

To Evaluate the Safety and Effectiveness of the Essure® ESS505 Device to Prevent Pregnancy in Women Who Are Seeking Permanent Contraception (*Study*)

Study design

This study is a prospective, multicentre, non*randomised, non*control, international study (*Study*).
- Female subjects are eligible to participate in the Study if she is seeking permanent contraception.
- Subjects must undergo informed consent process and consent in writing to participate in the Study.
- Subjects will be screened to determine enrolment eligibility as defined by Study Inclusion and Exclusion criteria.
- Pre*procedural medical history and physical examinations will be completed in accordance with regional standard of care with the inclusion of required pregancy testing.
- Subjects will undergo device placement procedure.
- Subjects will undergo TVU <=3 hour (not to exceed 3 hrs post placement) confirmation test post a successful placement procedure to confirm satisfactory insert location.
- Subjects follow*up care and discharge will be in accordance with regional standard of care.
- Subjects are requested to complete a three*month office visit (±14 business days) at which a pregnancy test will be administered. Subjects will be interviewed to determine subject*s clinical status i.e., incidence of pregnancy, occurence of extirpative surgeries and/or placement/device*related adverse events.
- Subjects are requested to complete a telephone interview at twelve months (±14 business days) post insert placement procedure.
- Subjects will be interviewed to determine clinical status i.e., incidence of pregnancy, occurrence of extirpative surgeries and/or placement/device*related adverse events.
- Subjects Study participation ends at the completion of the 12*month telephone interview or early withdrawal from the study.

Intervention

Subjects meeting study eligibility requirements will be clinically assessed and confirmed as appropriate for ESS505 placement.
ESS505 insert location will be evaluated and validated via TVU confirmation test performed <=3 hours post successful insert placement. If the TVU confirmation test is unsatisfactory, the insert placement and tubal occlusion will be evaluated by hysterosalpingogram (HSG).

Study burden and risks

The investigational device, ESS505, is developed to obviate the necessity for adjunct contraception, which is required by labelling with the ESS305 device, during the 3-month tissue in-growth period following device implant potentially effecting increased patient safety and health-care cost savings. Right after the bilateral implant (as confirmed by transvaginal ultrasound) of the ESS 505 device, the study subject can be confident that these protect against pregnancy, even if the closure of the fallopian tubes by tissue ingrowth will only fully occur three months after placement.

Contacts

Public
Conceptus Inc.

McCarthy Boulevard 1011
Milpitas CA 95035
US
Scientific
Conceptus Inc.

McCarthy Boulevard 1011
Milpitas CA 95035
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Females with age range 21 to 44 years;
2. Subjects seeking permanent contraception;
3. Subjects with body weight within range of 40 - 136 kilograms (90-300 pounds);
4. Subjects willing to accept the risk of pregnancy occurring whilst relying solely on the ESS505 for contraception;
5. Subjects for whom medical physical history indicate bilateral viable and patent fallopian tubes;
6. Subjects are able to comply with the protocol required follow-up visits (e.g., 3-month clinic visit, and the 12-month telephone interview);
7. Subjects provide written informed consent prior to enrolment;
8. Subjects who have sufficient mental capability to provide clinically relevant and reliable feedback regarding their experience wearing the device;
9. Subjects who agree that anonymised personal data will be made available to Study sponsor, requisite regional and international regulatory bodies;
10. Subjects have no contraindications for use as described in the ESS505 Instructions for Use (*IFU*), i.e. women with bilateral proximal tubal occlusion, women who have undergone fallopian tube sterilization, women with known endometrial or myometrial pathology which is likely to prevent access to the fallopian tube ostia, women who are post-menopausal, women with pelvic inflammatory disease, women who are pregnant or may become pregnant, women wih gynecologic malignancy, women with a general systemic disease or condition that could represent a risk, women who deliveres or terminated a pregnancy less than 6 weeks before Essure insert placement, women with a known allergy to contrast media, women with any general health condition that may represent, in the opinion of the physician, an increased potential risk associated with device use.

Exclusion criteria

1. Subjects with known proximal tubal occlusion in either fallopian tube;
2. Subjects who has undergone fallopian tube sterilisation procedure;
3. Subjects diagnosed with unicornuate uterus;
4. Subjects diagnosed with endometrial or myometrial pathology which may prevent fallopian tube ostia assess;
5. Subjects scheduled to undergo concomitant intrauterine procedures at the time of ESS505 placement; IUD removal is not considered a concomitant procedure. ;6. Subjects suspected of being or confirmed pregnant;

7. Subjects post-partum or undergone pregnancy termination <=6 weeks of scheduled ESS505 placement;
8. Subjects diagnosed with upper or lower pelvic infection;
9. Subjects for whom there are one or more contraindications for use as described in the ESS505 IFU;
10. Subjects with positive pre-procedure pregnancy test.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-01-2013
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	Essure ESS505 system
Registration:	No

Ethics review

Approved WMO

Date:	28-01-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	08-03-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-06-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-03-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL41877.100.12