A Multi-Center,Multi-National Clinical Study to Evaluate the Safety and Effectiveness of the ESSURE (Model ESS505) Device to Prevent Pregnancy in Women Who are Seeking Permanent Contraception

Published: 20-05-2014
Last updated: 24-04-2024

Evaluate the safety and effectiveness of the Essure System for Permanent Birth Control (Model ESS505) in preventing pregnancy

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

Summary

ID

NL-OMON40387

Source
ToetsingOnline

Brief title
permanent Birth Control System via follopian tube occlusion

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: funded by sponsor Bayer Healthcare LCC

Intervention

Keyword: contraception, device, permanent, sterilization

Outcome measures

Primary outcome

• Rate of confirmed pregnancies at 1 year among subjects told to rely

on ESS505 for contraception.

• Reliance rate: number of subjects told to rely on ESS505 after the

Essure confirmation test divided by the number of subjects who had insert

placement attempted.

Secondary outcome

• Occurrence of confirmed pregnancies at 10 years among subjects told to rely

on ESS505 for contraception.

• Safety of the ESS505 placement procedure defined as number of subjects who

experience an adverse event (AE) assessed as related to the

ESS505 placement procedure divided by the number of subjects in who at least 1

ESS505 was introduced into the fallopian tube.

• Safety of subsequent wearing of the insert defined as number of subjects who

experience an AE assessed as related to ESS505 wearing divided by the number of

subjects in whom the presence of an AE could be assessed.

Study description

Background summary

The Essure Permanent Birth Control System originally received Conformitè Europèenne (CE) Mark approval in February 2001 and United States (US) Food and Drug Administration (FDA) approval in November 2002. Currently, the Essure procedure is a clinically and commercially established hysteroscopic sterilization procedure. The Essure procedure is indicated for women who desire permanent birth control (female sterilization) by bilateral occlusion of the fallopian tubes.
The Essure procedure is conducted by using a transvaginal hysteroscopic approach. One small, flexible Essure insert is placed in the proximal portion of each fallopian tube. Upon release, the insert expands to conform to the fallopian tube, acutely anchoring itself until the insert elicits tissue in-growth. Prior clinical data demonstrate that total fallopian tube (tubal) occlusion occurs within three months of placement, resulting in permanent contraception.
The Sponsor has completed a design modification of the current commercially available Essure ESS305 into investigational device Model ESS505 (manufactured by Bayer HealthCare LLC). The ESS505*s primary design modification is the addition of a hydrogel component (plug) attached to the distal end of the insert. The hydrogel plug absorbs intrauterine fluids (i.e., water or saline) soon after placement, causing the hydrogel to swell, conform to the fallopian tube, and acutely occlude the target fallopian tube within one hour.

Study objective

Evaluate the safety and effectiveness of the Essure System for Permanent Birth Control (Model ESS505) in preventing pregnancy

Study design

This is a multi-center, multi-national clinical study to evaluate the safety and effectiveness of the ESS505 device to prevent pregnancy in women who are seeking permanent contraception.
Approximately 600 female subjects will be continuously enrolled in the study to receive the ESS505 and will be evaluated periodically for up to 1 year for pregnancy and AEs. Subjects will be followed for safety and efficacy for up to 10 years.
In order to evaluate the safety and effectiveness of ESS505 in preventing pregnancy, the study will have 2 co-primary endpoints and 3 secondary endpoints.

Intervention

• non-incisional permanent birth control (female sterilization) by occlusion of the fallopian tubes
• Subject will undergo insert placement procedure.
• Insert location will be evaluated and validated via Essure Confirmation Test performed post successful insert placement. Transvaginal Ultrasound (TVU) is the intended first-line confirmation test. If procedural events suggest the need for a hysterosalpingogram (HSG),as defined in the Essure Confirmation Test protocol, or the TVU confirmation test is equivocal or unsatisfactory, the insert placement and tubal occlusion will be evaluated by HSG. Upon a satisfactory confirmation test, subject will be instructed to rely on Essure for contraception.

Study burden and risks

Advantage: permanent contraception and no additional use of contraception during the first 3 months.
Risks:
- Pain, or cramps, vaginal blood loss, nausea or vomiting, fainting and / or dizziness just after the installation process.
- Possible perforation during the placement procedure fallopian tubes uterus, intestines, bladder, and blood vessels.
- Excessive moisture absorption due to the salt solution, during the placement.
- infections
- Shift of the device,
- Allergic reaction to the device
burdens:
- placement proceduer
- Follow-up visits
- Contact via phone or email
- Record of the first day of menstruation monthly

Contacts

Public
Bayer

Bayer HealthCare LLC 1011 McCarthy Boulevard
CA Milpitas 95035
US
Scientific
Bayer

Bayer HealthCare LLC 1011 McCarthy Boulevard
CA Milpitas 95035

US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

females 21-44 years
seeking permanent contraception
body weight 40-136 kg
sexually active
willing accept risk of pregnancy
medical physical history indicating bilateral viable & patient fallopian tubes
able to comply with 10 year FU visits

Exclusion criteria

known proximal tubal occlusion
ondergone fallopian tube sterilization
diagnosed endometrial or myometrial pathology
post-menopausal
upper or lower pelvic infection
suspected or confirmed pregnancy
gynecologic malignancy
pregnancy termination less then 6 weeks prior insert p0lacement
known allergy to all contrast media for use in HSG
unicornuate uterus

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):	21-08-2014
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	Essure 505
Registration:	No

Ethics review

Approved WMO

Date:	20-05-2014
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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
ClinicalTrials.gov	NCT01948882
CCMO	NL46730.075.13