A prospective, multicenter clinical trial to evaluate the safety and the effectiveness of the AEGEA Vapor System* for the treatment of excessive uterine bleeding.

Published: 22-10-2013
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To obtain the safety and effectiveness data necessary to support a Premarket Approval (PMA) Application to the U.S. Food and Drug Administration (FDA)

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Menstrual cycle and uterine bleeding disorders
Study type	Interventional

Summary

ID

NL-OMON41262

Source
ToetsingOnline

Brief title
Pivotal study

Condition

- Menstrual cycle and uterine bleeding disorders

Synonym
Excessive uterus bleeding, heavy menses

Research involving
Human

Sponsors and support

Primary sponsor: AEGEA Medical Inc.
Source(s) of monetary or material Support: AEGEA Medical Inc

Intervention

Keyword: Ablation, Endometrium, Menorrhagia, Vapor

Outcome measures

Primary outcome

Binary outcome of reduction of menstrual blood loss indicated by a Pictorial Blood Loss Assessment Chart (PBLAC) score of *75, 12 months after the endometrial ablation procedure.

Secondary outcome

The need for surgical or medical intervention to treat abnormal bleeding at any time within the first 12 months after treatment

Quality of Life using the Menorrhagia Impact Questionnaire 12 months after treatment

Patient satisfaction 12 months after treatment

Study description

Background summary

Abnormal uterine bleeding is a common problem among healthy premenopausal women with a relatively normal uterine cavity. Excessive menstrual loss, or menorrhagia, is a major problem for many women, with significant impact on their medical, social, economic and psychological well-being.

It is a condition that can be life-altering for women, resulting in anemia, fatigue and general

limitations on their normal daily activities. With a monthly blood loss of greater than 50 to 60 ml
per cycle, most women consuming an average Western diet will develop anemia.

In the past, hysterectomy was the treatment of choice when hormone therapy failed or was
contraindicated for women who were experiencing heavy menstrual bleeding. Although
hysterectomy has a 100% success rate (complete cessation of menstruation) and for some
women, high levels of satisfaction, it is a major surgical procedure with significant risks as well as
social and economic costs. Many women prefer less invasive surgical treatment and data
support that a less invasive procedure in which the endometrial lining is destroyed but the uterus
is preserved can be beneficial to women with menorrhagia.

Study objective

To obtain the safety and effectiveness data necessary to support a Premarket Approval (PMA) Application to the U.S. Food and Drug Administration (FDA)

Study design

Prospective, multi-center, single arm, open label clinical trial.

Intervention

The intervention consists of the removal of the endometrium by treating it with steam. For this purpose, a system is used that spreads steam in the uterus. In order to prevent damage occurs to the surrounding organs, the uterus is closed by means of little balloons that are part of the device that is placed in the uterus.

Study burden and risks

The study participation for subjects treated with the IDE design 1 consist of 4 clinical visits and 1 telephonic assessment. The follow-up will end with the 3-month follow-up visit.

The study participation for subjects treated with the IDE design 2 (Intent-to-Treat) consist of six clinical visits and 5 telephonic assessments. The follow-up will end after 36 months.

During the clinical visits the subject will undergo an assessment and will be

asked to complete questionnaires. The amount of time per visit is estimated to 30 minutes. Risks and benefits are further detailed in chapter 7 of the protocol.

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. Able to understand and has voluntarily signed and dated the IRB/EC approved informed consent form (ICF) prior to initiation of any screening or study-specific procedures;
2. Female subject from (and including) age 30 to 50 years;
3. Self-reported history of heavy menstrual bleeding in at least 3 of the last 6 months prior to screening;
4. Predictable cyclic menstrual cycles (consistent cycle duration days 21-35 days) over the last 6 months;

5. Excessive uterine bleeding, as documented by the Pictorial Blood Loss Assessment Chart (PBLAC), with a PBLAC score of *150 for one baseline cycle within three months prior to the endometrial ablation procedure for women who:
* Had at least 3 prior months (documented) failed medical therapy; or
* Had a contraindication to medical therapy (e.g., oral contraceptive pills, NSAIDs, failed D&C, iron, cox inhibitors, tranexamic acid, progestins); or
* Intolerant of medical therapy; or
* Refused medical therapy.
6. Pre-menopausal at enrollment as determined by FSH measurement *40 IU/L;
7. Normal PAP or ASCUS PAP with negative HR HPV, within the past year or at the time of screening or ASCUS HPV positive/low grade SIL who have been appropriately evaluated and managed;
8. Normal endometrial biopsy within the past 3 months or at the time of screening;
9. Willing to use reliable contraception through the initial 12 month time period following the AEGEA endometrial ablation procedure. Acceptable methods include:
* Female surgical sterilization (bilateral tubal sterilization), if completed prior to enrollment in the study
* Implantable contraceptive device (e.g., Essure® Birth Control or Adiana® Permanent Contraception System) if the tubal occlusion confirmation test has been completed and is satisfactory prior to enrollment in this study;
Vasectomy with semen analysis confirming no sperm present (based on subject report) and subject has a stable monogamous relationship throughout the initial 12 month follow-up phase
* Barrier contraceptives combined with spermicidal agent
* Monthly cyclic hormonal contraception (allowing a monthly withdrawal period) if the subject has used monthly cyclic hormonal contraception for *3 months prior to enrollment and is willing to continue the same monthly cyclic hormonal contraception through the initial 12 month follow-up phase. Note: subjects not on monthly cyclic hormonal contraceptives for a minimum of 3 months prior to enrollment must agree to not use any monthly cyclic hormonal contraceptive from enrollment through the initial 12 month follow-up phase except for the use of endometrial thinning agents prior to the endometrial ablation procedure. However, such subjects must agree to use another acceptable method of birth control as outlined above.
NOTE: Other than for purposes of endometrial thinning prior to the ablation procedure, subjects must not use hormonal contraception continuously (in order to suppress the menstrual cycle and thus not allow a withdrawal bleed) for the concomitant treatment of menorrhagia. There should be no concomitant use of any medication intended to treat menorrhagia.
10. Not currently taking any hormonal medication (e.g., estrogen, progestin) and have not been using any hormonal medication for a minimum of three months prior to study enrollment and agree not to use hormonal medication from the time of study enrollment through the initial 12 month follow-up phase except for the use of endometrial thinning agents prior to the endometrial ablation procedure;
11. Able and willing to use recommended hormonal agents for the thinning of the uterine lining, unless natural cycle timing will be used for this purpose, prior to the scheduled ablation

procedure;
12. Agrees to use sponsor provided catemenial products (menstrual pads and/or tampons) during the menstrual cycles that the PBLAC diary is used;
13. Able and willing to comply with all study tests, procedures, assessment tools and follow-up.

Exclusion criteria

1. Is pregnant as determined by urine or serum pregnancy test at screening or on day of procedure;
2. Desires future childbearing;
3. Presence of an intrauterine device/system (IUD/IUS) that the subject is unwilling to have removed prior to or at the time of the ablation procedure. Note: Subjects using a hormonal releasing IUD/IUS must have their device removed prior to ablation and then have one complete menstrual cycle at which time the baseline PBLAC diary may be completed. An IUD/IUS may not be re-inserted following ablation. The subject must agree to rely on either a barrier method plus spermicide, or vasectomy through the initial 12 month follow-up phase, as outlined above in inclusion (9).
4. Previous endometrial ablation procedure;
5. Evidence of an active sexually transmitted infection (STI) as determined by screening examinations or testing as required;
Evidence of active or recurrent chronic pelvic inflammatory disease (PID) as determined by screening examination;
7. Active infection of the genitals, vagina, cervix, uterus or urinary tract, at the time of the procedure, as detected by screening examination and patient symptoms;
8. Presence of active endometritis identified by clinical diagnosis;
9. Presence of bacteremia, sepsis or other active systemic infection confirmed by blood culture;
10. Suspected or confirmed gynecologic malignancy within the last five years as confirmed by histology;
11. Endometrial hyperplasia as confirmed by histology;
12. Known clotting defects or bleeding disorders (coagulopathy), based on patient history unless excluded by appropriate hematological examination;
13. Currently on anticoagulant therapy;
14. Hemoglobin <8gm/dl or considered by the investigator to be at risk for requiring a blood transfusion within 12 months;
15. Prior uterine surgery (except low transverse cesarean section) which could lead to weakening of the uterine wall (e.g. transmural myomectomy or classical cesarean section);
16. Currently on medications that could thin the myometrial muscle such as long-term steroid use (except inhaler or nasal therapy for asthma);
17. Severe dysmenorrhea that, in the opinion of the investigator, is secondary to adenomyosis (AUB-A) or where adenomyosis is suspected/known by prior evaluation;
Note: Severe dysmenorrhea is defined as pain with menses that interferes with the subject*s lifestyle and is unresponsive to over-the-counter (OTC) medications taken at the

usual dose.
18. Known uterine wall thickness of <1cm as measured by ultrasound;
19. Known bicornuate uterus;
20. Known uterine septum > 1/3 cavity length;
21. Known leiomyoma(s) that obstructs access to the uterine cavity or which prevents distension as determined by vaginal ultrasound, SIS or hysteroscopy;
22. Known uterine and/or cervical polyps *1cm in diameter or length or which, in the opinion of the investigator, contribute to the bleeding (AUB-P). Note: polyp removal will be allowed during screening but subjects must complete 2 menstrual cycles and then be re-evaluated against all inclusion and exclusion criteria prior to enrollment.
23. Known or suspected hydrosalpinx based on history or ultrasound at screening;
24. Known uterine length measurement of <6cm or >12 cm (external os to internal fundus);
25. Currently participating or planning future participation in a research study of an investigational drug or device during the course of this investigational study;
26. Known or suspected alcohol or drug abuse within 12 months prior to the screening visit;
27. An employee or relative of an employee of the Sponsor company (AEGEA Medical) or any Investigator Site employee or relative of employee working on the study;
28. Any general health condition that, in the opinion of the Investigator, could represent an increased risk for the subject.
29. Cannot tolerate anesthesia.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-03-2014
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	AEGEA Vapor System

Registration:	No

Ethics review

Approved WMO Date:	22-10-2013
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	23-01-2014
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	23-01-2015
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	13-02-2015
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	26-02-2015
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	08-12-2015
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	23-02-2016
Application type:	Amendment

Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

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	NL46249.072.13

Study results

Date completed:	16-07-2018
Actual enrolment:	18