The Post-Ablation Cavitary Evaluation (PACE) Clinical Trial;(A pilot, prospective, observational clinical trial to evaluate the uterine cavitary architecture of patients who have previously undergone endometrial ablation with the AEGEA Vapor System for treatment of heavy menstrual bleeding)

Published: 19-04-2016
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To determine the feasibility of hysteroscopically accessing and visualizing the uterine cavity greater than 24 months following a completed endometrial ablation with the AEGEA Vapor System

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Uterine, pelvic and broad ligament disorders
Study type	Observational invasive

Summary

ID

NL-OMON43089

Source
ToetsingOnline

Brief title
PACE

Condition

- Uterine, pelvic and broad ligament disorders

Synonym
adhesions within endometrial cavity, cavitary healing

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Ablation, Adhesion, Menorrhagia, Uterine cavity

Outcome measures

Primary outcome

Safety Endpoints: The safety endpoints will be an assessment of:

* Diagnostic hysteroscopy procedure-related serious adverse events

* The overall rate and severity of all reported adverse events

Primary Observational

Endpoint: The ability to access the endometrial cavity and perform a diagnostic hysteroscopic exam greater than 24 months following endometrial ablation with the AEGEA Vapor System. The extent of cavity access will be determined by how far the hysteroscope can be advanced into the uterine cavity. The distance of hysteroscope insertion into the cavity will be categorized as lower, middle or fundal cavity.

Secondary outcome

Other Observational

Endpoints:

* The ability to visualize the uterine cornua

* Presence, location and extent of adhesions within the endometrial cavity

* Presence, location and extent of residual endometrial tissue

* Presence and location of novel observations regarding cavitary healing

Study description

Background summary

This pilot clinical evaluation, conducted with the consent of subjects who previously participated in the AEGEA Phase II Feasibility Clinical Trial, will attempt to characterize the state of the endometrial cavity more than 24 months following treatment with the AEGEA Vapor System.

Study objective

To determine the feasibility of hysteroscopically accessing and visualizing the uterine cavity greater than 24 months following a completed endometrial ablation with the AEGEA Vapor System

Study design

A pilot, prospective, observational clinical trial to evaluate the uterine cavitary architecture of patients who have previously undergone endometrial ablation with the AEGEA Vapor System for treatment of heavy menstrual bleeding
This study will be conducted at up to 3 centers in The Netherlands where the AEGEA Phase II trial was previously completed. The hysteroscopy procedures will be done in a private practice office or outpatient setting.
Up to 17 subjects who previously completed the AEGEA Phase II Feasibility Clinical Trial (Protocol SE-2000), and were not withdrawn or lost-to-follow-up, will be consented and screened.
Study Duration: An estimated 2 months for subject enrollment and completion of the hysteroscopy procedures
Follow up: Subjects will exit the trial following the hysteroscopy. There are no follow up visits

Study burden and risks

There are no risks with relation to an investigative Medical Device. The only risks are that of a diagnostic hysteroscopy (not experimental). The possible

benefits for the patients outweigh the risks.

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 Ethics Committee (EC) approved informed consent form (ICF) prior to initiation of any screening or study-specific procedure;
2. Normal PAP or ASCUS PAP with negative HR HPV, within the past 5 years, or ASCUS HPV positive/low grade SIL who have been appropriately evaluated and managed;
3. Able and willing to comply with all study tests and procedures.

Exclusion criteria

1. Is pregnant as determined by urine pregnancy test during screening on the day of the hysteroscopy procedure;
2. Evidence of an active sexually transmitted infection (STI) as determined by study screening evaluation just prior to the planned hysteroscopy;
3. Active infection of the genitals, vagina, cervix, uterus or urinary tract, at the time of the hysteroscopy procedure, as detected by study screening examination and patient symptoms;
4. Suspected or confirmed gynecologic malignancy within the last five years as confirmed by histology;
5. Any general health condition that, in the opinion of the Investigator, could represent an increased risk for the subject;
6. Known allergy or intolerance to anesthesia.

Study design

Design

Study phase:	3
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-06-2016
Enrollment:	17
Type:	Actual

Ethics review

Approved WMO

Date:	19-04-2016
Application type:	First submission

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	NL57261.072.16