# Safety and Performance Evaluation for the AEGEA Global Endometrial (GEA) System in Women Scheduled to Undergo a Hysterectomy.

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| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Obstetric and gynaecological therapeutic procedures |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON35770

**Source**
ToetsingOnline

**Brief title**
VAPOR

### Condition

- Obstetric and gynaecological therapeutic procedures

**Synonym**
excessive menstrual loss, menorrhagia

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** AEGEA Medical Inc

**Source(s) of monetary or material Support:** Industrie;zie G2.

## Intervention

**Keyword:** AEGEA GEA VAPOR System, Hysterectomy, Performance, Safety

## Outcome measures

### Primary outcome

The primary endpoint is safety. This will be determined by the absence of

adverse events associated with the AEGEA-VAPOR treatment

### Secondary outcome

The performance of the VAPOR system will be measured by:

1. If satisfactory placement of the VAPOR-probe is achieved

2. If placement of the VAPOR probe is maintained throughout vapor delivery

3. If the target intra-uterine pressure can be achieved

4. Absence of clinically significant thermal injury in the cervical canal or

vagina based on inspection, histopathology and adverse event reporting.

5. Generator panel displays vapor delivery elapsed time, VAPOR probe pressure

and temperature

6. Intrauterine pressure does not exceed maximum vapor shut off limit (50 mm Hg)

7. Thermocouples (serosa and cervical) do not exceed 44 *C

8. Generator alarms operate as intended

# Study description

### Background summary

Heavy menstrual bleeding are common problems in pre-menstrual women. Hormonal therapy and hysterectomy are common treatments, of which especially the last one is very invasive for the patient. It is associated with it considerable risks. These days, endometrial ablation is becoming a more commonly used treatment method. During the ablation of the endometrium, the lining of the uterus is being removed and the uterus remains intact.

Global Endometrial Ablation Devices can be used to perform such endometrial ablations. An example is the Aegea GEA Vapor system, the medical device which is being tested in this study.

**Study objective**

The purpose of this study is to demonstrate that the use of the Vapor System is safe and effective. It will be tested in patients who were already planned to undergo a hysterectomy and the device thus has no therapeutic purpose in this particular study. VAPOR-treatment prior to hysterectomy allows the performance of the device under test while the risk for the patient are minimized. Also, the degree of ablation of the endometrium will be evaluated in pathological examination of tissue after the treatment. The results of this study will determine whether the Vapor-system can be used for ablation in the future in the assigned patient population.

**Study design**

This is a prospective, non-randomized, multi-center and open-label study

**Study burden and risks**

The risk for the subjects in this study are estimated to be low. In this study, a peri-hysterectomy is being performed to assess the safety and efficacy of the Vapor endometrial ablation system. By treating/testing the patient prior to hysterectomy, the risk of damage to surrounding organs by the steam will be minimized. Also, the temperature of the outer wall of the uterus will be monitored to confirm that the procedure is safe for future application in the intended patient population (future research). No incisions are made**.

The stresses on the subjects will also be low because the patients already on the waiting list for a hysterectomy and no need to fill in questionnaires or the like.

In conclusion, the burden and risks for these patients will be low. And thorough investigation of the VAPOR device will inform us whether it is a safe and effective device for future ablations.

# 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. Age 30-50 years
2. Patient consented to undergo hysterectomy prior to being approached to this study
3. Functional endometrium presently visible on ultrasound within 30 days
4. Able to provide written informed consent
5. Fundal length <= 12 cm
6. Normal PAP results within 6 months prior to enrollment
7. Normal endobiopsy results within 30 days prior to enrollment
8. Negative pregnancy test within 1 day prior to procedure

### Exclusion criteria

1. Post-menopausal
2. Planned hysterectomy involving uterine morcellation
3. Active pelvic inflammatory disease
4. Gynaecological malignancy within the past 5 years
5. Known/suspected abdominal/ pelvic cancer
6. Septate uterus
7. Abnormal PAP results unless appropriately evaluated
8. Submucosal myomas or polyps > 1cm in diameter
9. Patients with intramural or subserosal fibroids that either distort the uterine cavity or are > 4 cm in diameter
10. Cervical length < 2 cm
11. Previous endometrial ablation procedure or classical c-section or transmural myomectomy
12. Patients with anatomy that is identified by the PI to be at risk for inadequate cervical seal with the Vapor Probe balloon
13. Any general health condition, which, in the opinion of the PI, could represent an increased risk for the potential patient.

## Study design

### Design

**Study type:** Observational invasive

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

### Recruitment

NL

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| Recruitment status: | Pending |
| Start date (anticipated): | 01-07-2011 |
| Enrollment: | 45 |
| Type: | Anticipated |

## Ethics review

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| Approved WMO Date: | 27-10-2011 |
| Application type: | First submission |
| Review commission: | IRB Nijmegen: Independent Review Board Nijmegen (Wijchen) |
| Approved WMO Date: | 03-01-2012 |
| 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 | NL36727.072.11 |