ABLATE Study.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22943

Source
Nationaal Trial Register

Brief title
ABLATE: Abnormal BLeeding Ablation Treatment Evaluation

Health condition

Menorrhagia
Abnormal Uterine Bleeding

Sponsors and support

Primary sponsor: AEGEA Medical
2686 Middlefield Road, Suite A
Redwood City, California 94063
United States of America
Source(s) of monetary or material Support: AEGEA Medical

Intervention

Outcome measures

Primary outcome

1. Primary effectiveness endpoint is the reduction in menstrual blood loss as measured by an alkaline hematin score of < 80 mL at 3 months;

2. Procedural safety: Defined by the absence of device or procedure related serious adverse events within 14 days of the ablation procedure.

Secondary outcome

Patient's subjectively reported improvement based on 6 month post-procedure Multi-Attribute Utility Assessment (Menorrhagia Questionnaire) as compared to Baseline.

Study description

Background summary

The purpose of this study is to evaluate the feasibility (safety and effectiveness) of the AEGEA GEA System to reduce menstrual blood loss in women with a history of menorrhagia due to benign causes. Subjects will undergo alkaline hematin screening testing to identify 30 who are appropriate for treatment with the goal to have 20 subjects who complete the three-month follow-up. Participants will undergo a follow-up assessment 2 weeks following the procedure and at 6 weeks, 3 months, 6 months, 9 months 12 months, 18 months and 24 months.

Study objective

The purpose of this study is to evaluate the feasibility (safety and effectiveness) of the AEGEA GEA System to reduce menstrual blood loss in women with a history of menorrhagia due to benign causes.

Study design

1. Screening;

2. Ablation Procedure;

3. 2 and 6 week follow-up;

4. 3, 6, 12 and 24 month follow-up.

Intervention

Endometrial ablation is a minimally invasive treatment of menorrhagia that eliminates the the endometrial layer of the uterine cavity while preserving the uterus.

Contacts

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Eligibility criteria

Inclusion criteria

1. Women of age ≥ 30 and ≤ 50 years;

2. Pre-menopausal (absence of hot flashes);

3. Monthly menstrual cycles (cycle days 21-35) over the last 6 months;

4. Self-reported history of heavy menstrual bleeding as noted by flooding or interfering with work or social activities in 3 months of the past 6 months;

5. Documented history of excessive uterine bleeding defined by:

A. Alkaline hematin score of ≥ 160 mL for one month, within three months prior to the ablation procedure (this test may be repeated one time if the initial result is <160 mL and >120 mL); AND;

B. Previously failed, did not tolerate or refused medical therapy (oral contraceptive pills, NSAIDs, failed D&C or cyclic progestin therapy).

6. Evidence of normal PAP smear, including Class II/ASCUS that has been evaluated, within the last 6 months;

7. Evidence of normal endometrial biopsy results within the last 6 months;

8. Not currently using any hormonal contraceptives (for example, oral or injectable) and have not been using any hormonal contraceptives for a minimum of three months prior to study enrollment, and agree to not use any hormonal contraceptives from the time of study enrollment through the first 12 months following treatment, OR

Are currently using hormonal contraceptives, (for example, oral or injectable) and have been using hormonal contraceptives for a minimum of three months prior to study enrollment, and agree to continue to use hormonal contraceptives from the time of study enrollment through the first 12 months following treatment;

9. Are not currently taking any hormonal supplements (for example, estrogen) and have not been using any hormonal supplements for a minimum of three months prior to study enrollment and agree not to use hormonal supplements from the time of study enrollment through the first 12 months following treatment;

10. Do not desire current or future childbearing;

11. Not currently pregnant;

12. Do not desire to have an intrauterine device (IUD) placed or Essure or Adiana devices placed during the first 12 months following treatment
m);

13. Agrees to use sponsor provided sanitary pads and tampons during the conduct of the Alkaline Hematin tests;

14. Able and willing to comply with all study tests, procedures and assessment tools;

15. Able and willing to sign the Informed Consent Form;

16. Agrees to follow up period as outlined.

Exclusion criteria

1. Hemoglobin < 4.65 mmol/L or considered by the investigator at risk for requiring blood transfusion within 12 months;

2. Known active pelvic inflammatory disease or genital tract infection (e.g., cervicitis, vaginitis, endometritis, salpingitis, or cystitis), or active urinary tract infection;

3. Clotting defects or bleeding disorders (based on history) or on anti-coagulant therapy;

4. A patient with a history, known or suspected abdominal/pelvic cancer, endometrial carcinoma (uterine cancer) or unresolved potentially premalignant conditions such as complex endometrial hyperplasia;

5. Uterine length > 12 cm;

6. Submucosal myoma(s) > 4 cm diameter or that distort the uterine cavity;

7. Uterine and/or cervical polyps > 1 cm in diameter;

8. Intramural myomas that are > 4 cm in diameter or that distort the uterine cavity;

9. Bicornuate uterus;

10. Known or suspected hydrosalpinx;

11. Previous endometrial ablation procedure;

12. Desire for complete amenorrhea;

13. Known anatomical condition (e.g., history of previous classical cesarean section or transmural myomectomy, or uterine wall thickness < 1 cm) or pathologic condition that could lead to weakening of the myometrium;

14. Currently participating in another clinical trial;

15. The Investigator determines enrollment in the study is not appropriate for any reason.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-01-2012
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-03-2012
Application type:	First submission

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
NTR-new	NL3202
NTR-old	NTR3353
Other	AEGEA Medical : SE-2000
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A