Evaluation of Menstrual Bleeding in Women with Menorrhagia Significant Enough to Seek Treatment

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The purpose of this study is to quantify the amount of menstrual bleeding in participants with menorrhagia and its correlation to the overall impact of health as measured by the Menorrhagia Questionnaire.

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

Summary

ID

NL-OMON35386

Source
ToetsingOnline

Brief title
Baseline study

Condition

- Menstrual cycle and uterine bleeding disorders

Synonym
excessive uterine bleeding, menorrhagia

Research involving
Human

Sponsors and support

Primary sponsor: Factory, CRO for medical devices
Source(s) of monetary or material Support: Zie G2

Intervention

Keyword: Evaluation, Menorrhagia

Outcome measures

Primary outcome

The purpose of this study is to evaluate the amount of menstrual bleeding in patients with menorrhagia and its correlation to the overall impact of health as measured by the Alkaline Hematin test and Menorrhagia Questionnaire. As part of the evaluation, participants will be screened for anemia as an indicator of the amount of blood loss experienced and reported.

Secondary outcome

Not applicable

Study description

Background summary

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 experiencing 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. If left untreated, it may be associated with subsequent morbidity including dysmenorrhea, hospitalization, red blood cell transfusions and chronic pain. First line treatment includes hormonal therapy and/or treatment with non-steroidal anti-inflammatory drugs (NSAIDS). When these fail endometrial ablation can be an effective minimally invasive surgical treatment.
In order to evaluate new technologies, particularly with the objective of gaining regulatory approvals for marketing, patient outcomes need to be quantified in terms of amount and duration of menstrual bleeding, overall impact on health and patient satisfaction to allow objective comparisons between pre-treatment and post-treatment.

The study planned in this protocol is intended to evaluate participants

believed by their physicians, based on participant self-identification, to have significant menorrhagia, and its correlation to overall state of health as measured on the Menorrhagia Questionnaire tool. Participants who are found to require treatment for menorrhagia may be eligible for enrollment into a planned follow-on investigational treatment protocol to evaluate the safety and effectiveness of the AEGEA GEA System. No treatment will be offered as a part of this protocol.

Study objective

The purpose of this study is to quantify the amount of menstrual bleeding in participants with menorrhagia and its correlation to the overall impact of health as measured by the Menorrhagia Questionnaire.

Study design

This study is:

• Prospective
• Multi-centered
• Single-arm (non-randomized)
• Data collection only

Study burden and risks

There is minimal risk associated with the needle stick for phlebotomy. Risks are limited to hematoma and infection at the site of the needle stick. These risks are minimized by using only staff skilled in phlebotomy.

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

Due to the nature of the study, only women will be enrolled in this study. Candidates for this study must meet ALL of the following criteria:
a) Women of age 30-50 years
b) Pre-menopausal
c) History of excessive uterine bleeding defined by:
• Heavy menstrual bleeding as noted by flooding or interfering with work or social activities
• Previously failed, did not tolerate or refused medical therapy (oral contraceptive pills, NSAIDs, failed D&C or cyclic progestin therapy)
d) Evidence of normal PAP smear within the last 6 months, if available
e) Normal endometrial biopsy results within the last 6 months, if available
f) Is not using hormonal contraception and agrees to not use hormonal contraception for study duration
g) Does not desire current or future childbearing
h) Does not desire to have an intrauterine device (IUD) placed or Essure or Adiana devices placed while participating in this study
i) Able and willing to comply with all study tests, procedures and assessment tools
j) Able and willing to sign the Informed Consent Form;
k) Agrees to follow up period as outlined, and use of sponsor provided sanitary pads and tampons

Exclusion criteria

Candidates will be excluded if ANY of the following conditions apply:
a) Desires treatment for menorrhagia within the next 2 months
b) Hemoglobin <8gm/dl or considered by the investigator at risk for requiring blood transfusion within 12 months
c) Known active pelvic inflammatory disease or genital tract infection (cervicitis, vaginitis,

endometritis), or active urinary tract infection
d) Clotting defects or bleeding disorders (based on history) or on anti-coagulant therapy
e) Abnormal PAP smear
f) Malignant pathology, documented or suspected, based on endometrial biopsy
g) History of gynecologic malignancy within the past 5 years
h) Uterine and/or cervical polyps > 1 cm in diameter
i) Intramural fibroids that are > 4 cm in diameter
j) Septate uterus
k) Known or suspected hydrosalpinx
l) Previous endometrial ablation procedure
m) Desire for complete amenorrhea, once treatment is sought
n) Known anatomical condition (e.g., history of previous classical cesarean section or transmural myomectomy) or pathologic condition (e.g., long term medical therapy) that could lead to weakening of the myometrium.
o) Currently pregnant
p) Desire for future fertility
q) Current use of any Intrauterine Device (IUD), Essure, Adiana, or similar device or desire for placement before completion of the study
r) Current use of hormonal contraception or use of endometrial suppression therapy within three month of AH screening
s) The investigator determines enrollment in the study is not appropriate for any reason

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2011
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO Date:	21-11-2011
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	15-12-2011
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	NL37734.072.11