Prevalence of bleeding disorders in women with menorrhagia

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Main: To confirm the findings of our previous, explorative study that the overall FXI plasma levels in patients with menorrhagia are lower than in controls. Secondary: To establish the prevalence of FXI mutations/polymorfisms in patients with...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Observational invasive

Summary

ID

NL-OMON39998

Source
ToetsingOnline

Brief title
Menorrhagia and bleeding disorders

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Chromosomal abnormalities, gene alterations and gene variants

Synonym
heavy menstrual bleeding, menorrhagia

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Stichting ter Bevordering van Onderzoek/Onderwijs op het gebied van Hemostase;Trombose en Rheologie

Intervention

Keyword: Bleeding disorders, Factor XI levels, Menorrhagia

Outcome measures

Primary outcome

Plasma FXI levels.

Secondary outcome

FXI gene mutations/polymorfisms.

Prevalence of bleeding disorders in patients with menorrhagia.

Study description

Background summary

Menorrhagia is a common problem among women in the reproductive age. At least 5 -10% of women in reproductive age will seek medical attention for menorrhagia. Menorrhagia can be caused by a wide range of disorders. In the past decade underlying bleeding disorders, such as Von Willebrand disease, have been recognized as an important etiologic and/or contributory factor. Nevertheless, haemostatic evaluation is uncommon in routine gynaecological practice. Preliminary results from our previous study of 102 patients with menorrhagia and 28 volunteers showed, unexpectedly, that patients had significantly lower levels of factor XI (FXI) compared to controls (100 vs 125 IU/dL; $p<0.001$) Of all the patients, four had a FXI level deficiency (<70%). This finding needs to be replicated and explained by analysis of the factor XI gene.

Study objective

Main: To confirm the findings of our previous, explorative study that the overall FXI plasma levels in patients with menorrhagia are lower than in controls.
Secondary: To establish the prevalence of FXI mutations/polymorfisms in patients with menorrhagia in comparison to controls.
To establish the prevalence of other bleeding disorders in women with menorrhagia.

Study design

Observational study.

Study burden and risks

Burden and risks: patients are asked to fill out a questionnaire (duration around 15 minutes). 30 cc extra blood will be taken when blood is drawn for other reasons, such as full blood count (i.e. no extra venapunction). The healthy female volunteers are asked to fill out the same questionnaire and we will be taking 30 cc of blood for multiple samples in a single venapunction. There are no benefits for the healthy volunteers. The patients get a coagulation work-up. If we find a bleeding disorder, the patient and the treating physician will be informed about the bleeding disorder. Besides the risk associated with venapunction, there are no risks for participants of the study.

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

- Healthy controls with regular normal menstrual bleeding
Age *18 years
Written informed consent
- Patients with regular heavy menstrual bleeding (<=menorrhagia)
Age *18 years
Written informed consent

Exclusion criteria

- Healthy controls with:
1. postmenopausal, postcoital or intermenstrual bleeding.
2. an intra-uterine device or hormonal treatment.
3. anticoagulant, antithrombotic therapy or use of non-steroidal anti-inflammatory drugs (NSAIDs).
- Patients with:
1. postmenopausal, postcoital or intermenstrual bleeding.
2. an intra-uterine device or hormonal treatment.
3. anticoagulant, antithrombotic therapy or use of non-steroidal anti-inflammatory drugs (NSAIDs).

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	19-09-2013
Enrollment:	287
Type:	Actual

Ethics review

Approved WMO Date:	12-08-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL42716.042.12