Systemic fibrinolysis in women with menorrhagia

Published: 25-09-2014
Last updated: 15-05-2024

Main: Investigate the cyclic variation in clot lysis time in women with HMB in comparison to controls. Secondary:- Investigate the cyclic variation in TAFI, PAI-1, tPA, PI, thrombin generation, fibrinogen, fibrin clot permeability and confocal...

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

Summary

ID

NL-OMON42249

Source
ToetsingOnline

Brief title
Menorrhagia and systemic fibrinolysis

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Menstrual cycle and uterine bleeding disorders

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: Clot lysis time, Fibrinolysis, Menorrhagia, Menstrual cycle

Outcome measures

Primary outcome

clot lysis time in patients and controls.

Secondary outcome

Thrombin activatable fibrinolysis inhibitor, plasminogen activator inhibitor-1,

tissue plasminogen activator, plasmin inhibitor, thrombin generation,

fibrinogen, fibrin clot permeability and confocal microscopy analysis of fibrin

clots .

Progestagen and Body Mass Index.

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. Heavy menstrual bleeding (HMB) is known to be associated with gynaecological abnormalities and can also be associated with a wide range of haemostatic disorders.
There is also evidence that fibrinolysis in the endometrium plays an important role in menstruation. In women with menorrhagia increased fibrinolytic activity was observed in the menstrual fluid which suggested that this might be a contributing factor in the etiology of heavy menstrual bleeding. Notably, the role of systemic fibrinolysis in women with HMB was not studied yet. Results from our previous study showed no increased systemic fibrinolysis in women with HMB. Inhibitors of fibrinolysis (thrombin activatable fibrinolysis inhibitor (TAFI) and plasmin inhibitor (PI)) were even higher in patients with heavy menstrual bleeding. An explanation why we found no increased systemic fibrinolysis could be the moment of testing in the menstrual cycle. Probably there is cyclic variation in menstruating women with menorrhagia. This hypothesis needs to be tested by measuring fibrinolytic parameters during the

menstrual cycle.

Study objective

Main: Investigate the cyclic variation in clot lysis time in women with HMB in comparison to controls.
Secondary:- Investigate the cyclic variation in TAFI, PAI-1, tPA, PI, thrombin generation, fibrinogen, fibrin clot permeability and confocal microscopy analysis of fibrin clots in women with HMB in comparison to controls.
- Investigate the ovulatory menstrual cycle by measuring progestagen.

Study design

Observational cross-sectional study.

Study burden and risks

Burden and risks: patients are asked to fill out a questionnaire (duration around 15 minutes). For patients of the UMCG 18 cc of extra blood will be taken when blood is drawn for other reasons, such as full blood count (i.e. no extra venapunction). For the patients of the Martini Hospital this venapunction is not performed at the same time of a routine laboratory measurement. The controls or the healthy female volunteers are asked to fill out the same questionnaire and we will be taking 18 cc of blood for multiple samples in a single venapunction. The patients and controls need to come back 3 times for blood withdrawal. This will be at week 2 (day 12-16, 18 cc of blood), week 3 (day 19-23, 23 cc of blood) and week 4 (day 26-30, 18 cc of blood). There are no benefits for the patients and controls.

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 menstrual blood loss.
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 (NSAID*s).
4. a Body Mass Index >30 kg/m2.
- 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 (NSAID*s).
4. uterine fibroids > 2 cm in diameter.
5. a Body Mass Index >30 kg/m2.
6. PBAC-score <200 points.

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):	14-01-2015
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	25-09-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	13-07-2015
Application type:	Amendment
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

ID: 22702
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL50151.042.14
OMON	NL-OMON22702