Fibrinolytic parameters in women with heavy menstrual bleeding

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22702

Source
Nationaal Trial Register

Brief title
Menorrhagia and systemic fibrinolysis

Health condition

Heavy menstrual bleeding / Hevig menstrueel bloedverlies
Menorrhagia / menorrhagie
Menstrual cycle / menstruele cyclus
Fibrinolysis / fibrinolyse
Clot lysis time / Clot lysis tijd

Sponsors and support

Primary sponsor: University Medical Centre Groningen
Department of Hematology
Prof. J.C. Kluin-Nelemans
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Source(s) of monetary or material Support: University Medical Centre Groningen
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Intervention

Outcome measures

Primary outcome

- Investigate the cyclic variation in clot lysis time in women with HMB in comparison to controls.

Secondary outcome

- Investigate the cyclic variation in TAFI, PAI-1, tPA, PI, thrombin generation, fibrin clot permeation and confocal microscopy analysis of fibrin clots in women with HMB in comparison to controls.

- Investigate the ovulatory menstrual cycle by measuring progestagen.

Study description

Background summary

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. The role of systemic fibrinolysis in women with heavy menstrual bleeding was studied and showed no increased systemic fibrinolysis in women with heavy menstrual bleeding. Certain fibrinolytic parameters 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 in women with HMB and controls with normal menstrual bleeding.

Study design

Overview of measurements during the study

- Questionnaire: week 1

- PBAC: week 1

- Blood: Fibrinolytic parameters: week 1,2,3, 4

- Blood: Progesterone: week 3

Intervention

Patients ar asked to fill out a questionnaire and to withdraw blood 4 times (one time every week, for 4 weeks in a row).

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion criteria for patients:

- Patients with regular heavy menstrual bleeding (=menorrhagia).

- Age over 18 years.

- Written informed consent.

Inclusion criteria for healthy controls with regular menstrual blood loss:

- Age over 18 years.

- Written informed consent.

Exclusion criteria

Exclusion criteria for patients:

- Patients with postmenopausal, postcoital or intermenstrual bleeding

- Patients with an intra-uterine device or hormonal treatment.

- Patients with anticoagulant, antithrombotic therapy or use of non-steroidal anti-inflammatory drugs (NSAID’s).

- Patients with uterine fibroids > 2 cm in diameter.

- Patients with a Body Mass Index >30 kg/m2.

- Patients with a Pictorial Bleeding Assessment Chart-score <200.

Exclusion criteria for healthy controls:

- Women with postmenopausal, postcoital or intermenstrual bleeding.

- Women with an intra-uterine device or hormonal treatment.

- Women with anticoagulant, antithrombotic therapy or use of non-steroidal anti-inflammatory drugs (NSAID’s).

- Women with a Body Mass Index >30 kg/m2.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2014
Enrollment:	20
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 42249
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4671
NTR-old	NTR4823
CCMO	NL50151.042.14
OMON	NL-OMON42249

Study results

Summary results
Our previous research on this topic is published:
Titel: No increased fibrinolysis in women with heavy menstrual bleeding.
Authors: Wiewel-Verschueren S, Knol HM, Lisman T, Bogchelman DH, Kluin-Nelemans JC, van der Zee AG, Mulder AB, Meijer K.

Published: J Thromb Haemost. 2014 Sep;12(9):1488-93.