Fibrinolytic parameters in women with heavy menstrual bleeding

Gepubliceerd: 11-09-2014 Laatst bijgewerkt: 15-05-2024

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22702

Bron
Nationaal Trial Register

Verkorte titel
Menorrhagia and systemic fibrinolysis

Aandoening

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

Ondersteuning

Primaire sponsor: University Medical Centre Groningen
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Overige ondersteuning: University Medical Centre Groningen
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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Onderzoeksopzet

Overview of measurements during the study

- Questionnaire: week 1

- PBAC: week 1

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

- Blood: Progesterone: week 3

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-11-2014

Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 42249
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
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.