Heavy MEnstrual bleeding in premenopausal women treated with DirEct oral Anticoagulants - the MEDEA study

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A switch to thrombininhibitor dabigatran or addition of tranexamic acid to the factor Xa inhibitor may be effective in women who experience heavy menstrual bleeding during anticoagulant treatment with factor Xa inhibitors.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20525

Bron
NTR

Verkorte titel
MEDEA

Aandoening

Heavy menstrual bleeding associated with direct oral anticoagulants/factor Xa inhibitors.

Ondersteuning

Primaire sponsor: Amsterdam University Medical Centers - location AMC
Overige ondersteuning: Boehringher Ingelheim BV

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The difference in PBAC-score before and after randomisation.

Toelichting onderzoek

Achtergrond van het onderzoek

Treatment with direct oral anticoagulants (DOACs), in particular factor Xa inhibitors, is associated with an increased risk of abnormal uterine bleeding, particularly heavy menstrual bleeding (HMB), in premenopausal women. It has been suggested that abnormal uterine bleeding, including HMB and intermenstrual bleeding, occurs less frequently during treatment with the thrombin inhibitor dabigatran. The association between the type of DOACs (factor Xa versus thrombin inhibitor) and HMB has not been fully elucidated and merely assumptions on possible mechanisms exist. Use of tranexamic acid during the menstrual period may be effective in patients with HMB, but prospective data regarding efficacy and safety in patients with an indication for anticoagulant treatment are lacking. DOACs are prescribed increasingly and a direct comparison between dabigatran and a factor Xa inhibitor, as well as an evaluation of the effects of additional tranexamic acid in women with HMB is highly relevant for clinical practice. All available methods to measure menstrual blood loss have limitations, but the pictorial blood loss assessment chart (PBAC) is a simple clinical tool and has adequately been validated as a semi-objective assessment of menstrual blood loss and pattern of menstrual cycle.
The disease specific menstrual bleeding questionnaire (MBQ) is a valid patient-reported outcome measure for heavy menstrual bleeding.

Doel van het onderzoek

A switch to thrombininhibitor dabigatran or addition of tranexamic acid to the factor Xa inhibitor may be effective in women who experience heavy menstrual bleeding during anticoagulant treatment with factor Xa inhibitors.

Onderzoeksopzet

* Screening
* Enrolment/Visit 1
* 1 month - visit 2 (telephone)
* 2 months - visit 3 (telephone)
* End of Study - visit 4

Onderzoeksproduct en/of interventie

Eligible patients will be randomised in a 1:1:1 ratio to switch to dabigatran, to continue treatment with the factor Xa inhibitor without intervention, or to continue treatment with the factor Xa inhibitor with the addition of 1 gram tranexamic acid three times a day during the first four days of the menstrual period.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- premenopausal women
- age ≥18 years
- anticoagulant treatment with a factor Xa inhibitor
- indication for anticoagulant treatment >3months after inclusion
- heavy menstrual bleeding and a PBAC-score >150
- use of adequate contraceptive methods during study participation (this is advised to any woman on factor Xa inhibitors during fertile ages, regardless of study participation)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- PBAC-score ≤150
- Postmenopausal women; women >12 consecutive months of spontaneous amenorrhea

- concomitant use of hormonal therapy as a new intervention for HMB
- pregnancy or currently planning for pregnancy
- active malignancy or treatment with chemotherapy/radiotherapy
- cervical preneoplastic lesions
- contra indication for the registered products dabigatran or tranexamic acid
- any condition that, as judged by investigator, would place the subject at an increased risk of harm if she participated in the study

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	03-02-2020
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
N/A

Ethische beoordeling

Positief advies

Datum:	13-05-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7760
Ander register	CCMO / METC AMC : METC 2019_126

Resultaten

Samenvatting resultaten
N/A