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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20525

Source
NTR

Brief title
MEDEA

Health condition

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

Sponsors and support

Primary sponsor: Amsterdam University Medical Centers - location AMC
Source(s) of monetary or material Support: Boehringher Ingelheim BV

Intervention

Outcome measures

Primary outcome

The difference in PBAC-score before and after randomisation.

Secondary outcome

• Quality of life assessment, by means of the disease-specific menstrual bleeding questionnaire (MBQ) and a standardized 36-item short form survey (SF-36) for Quality-of-Life assessment
• Laboratory values, including haemoglobin and iron-status at baseline and end of study
• Any bleeding event other than heavy menstrual bleeding
• Any event requiring a change in anticoagulant treatment, i.e. a newly onset thromboembolic event while on anticoagulant treatment, interruption of anticoagulant treatment before minor or major surgical procedures

Study description

Background summary

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.

Study objective

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.

Study design

* Screening
* Enrolment/Visit 1

* 1 month - visit 2 (telephone)
* 2 months - visit 3 (telephone)
* End of Study - visit 4

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

- 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)

Exclusion criteria

- 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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	03-02-2020
Enrollment:	120
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

Ethics review

Positive opinion

Date:	13-05-2019
Application type:	First submission

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
NTR-new	NL7760
Other	CCMO / METC AMC : METC 2019_126

Study results

Summary results
N/A