Risico op en oorzaken van abnormaal menstrueel bloedverlies in vrouwelijke proefpersonen in de vruchtbare leeftijd met trombosebeen of longembolie

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24079

Source
Nationaal Trial Register

Brief title
the TEAM-VTE study

Health condition

Venous thromboembolism
Menstrual bleeding
Anticoagulation

Sponsors and support

Primary sponsor: University of Leiden
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Incidence of new-onset abnormal menstrual bleeding

Secondary outcome

1) Rate of clinical relevant non-major and major (menstrual) bleeding according to the ISTH criteria;

2) Change in rate of abnormal menstrual bleeding after diagnosis of VTE after initiation of anticoagulants, and during the follow-up period;

3) Impact of new-onset abnormal menstrual bleeding on QoL as assessed with the MBQ, VEINS-QOL and PEmb-QoL;

4) Predictors of new-onset abnormal menstrual bleeding;

5) Changes in contraceptive measures during the study: details, incidence, causes and effect on primary endpoint and recurrent VTE;

6) Changes in anticoagulation therapy: details, incidence, causes and effect on primary endpoint and recurrent VTE;

7) Presence of underlying gynaecological or other morbidities as explanation for abnormal menstrual bleeding.

Study description

Background summary

This study is an international, multicenter, academically sponsored, observational study, that focusses on fertile female patients with proven symptomatic deep vein thrombosis of the legs (DVT) or acute pulmonary embolism (PE). The incidence and severity of abnormal menstrual bleeding will be assessed for each menstrual period and correlated to quality of life. Causes of abnormal menstrual bleeding other than active anticoagulant treatment will be assessed. Treatment of abnormal menstrual bleeding (all within routine clinical care) will be evaluated for efficacy and safety.

Study objective

After initiation of anticoagulant therapy in females diagnosed with DVT or PE in their fertile age, 30% of patients will develop abnormal menstrual bleeding leading to decreased quality of life.

Study design

Patients are included shortly after a new diagnosis of DVT or PE and followed for 6 months or discontinuation of anticoagulant therapym whichever comes first.

Intervention

None

Contacts

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Eligibility criteria

Inclusion criteria

Consecutive female patients between the ages of 18 and 50 with child bearing potential and objectivated, symptomatic VTE, who fulfil all the inclusion criteria and meet none of the exclusion criteria, are eligible for inclusion.

Inclusion criteria:

1) Ability of subject to understand the character and individual consequences of this clinical study;

2) Signed and dated informed consent of the subject available before the start of any specific study procedures;

3) Age ¡Ý18 years and ¡Ü 50 years;

4) Confirmed symptomatic first or recurrent VTE;

a. DVT: incompressibility of proximal or distal veins of the affected leg by compression ultrasonography or venous filling defect on multi-detector computed tomography venography. The diagnosis of ipsilateral recurrent DVT is defined as a CUS that shows incompressibility of a different venous segment than at the reference CUS examination, or in case of a pronounced increase in vein diameter (¡Ý4 mm) of a previous non-compressible venous segment, or by an abnormal signal of Magnetic resonance direct thrombus imaging (MRDTI);

b. PE: both first and recurrent PE are diagnosed in case of at least one filling defect in the pulmonary artery tree on multi-detector computed tomography pulmonary angiography (CTPA) up to the subsegmental level, or high probability result of ventilation perfusion scintigraphy;

5) Childbearing potential, i.e. with active menstrual cycle with or without hormonal regulation of any kind initiated for reasons of either contraception or for treatment of abnormal menstrual bleeding;

6) Inclusion before the first day of next menstrual cycle after VTE diagnosis or within 1 month after the VTE diagnosis, whichever comes first.

Exclusion criteria

Exclusion criteria:

1) Woman between the ages of 18 and 50 who were subjected to hysterectomy or chemically induced menopause;

2) Woman between the ages of 18 and 50 with premature menopause (established before study inclusion);

3) Planned treatment with parenteral anticoagulation (and no switch to oral drugs);

4) Medical or psychological condition that would not permit completion of the study or signing of informed consent, including life expectancy less than 6 months, or unwillingness to sign informed consent;

5) Non-compliance or inability to adhere to the follow-up visits;

6) Pregnancy or post-partum (first three months) associated VTE;

7) Active in vitro fertilization (IVF) treatment or planned IVF treatment during the study period.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2018
Enrollment:	210
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-08-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55518
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7238
NTR-old	NTR7437
CCMO	NL64567.058.17
OMON	NL-OMON55518

Study results

Summary results
None