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

Gepubliceerd: 15-08-2018 Laatst bijgewerkt: 15-05-2024

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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24079

Bron
Nationaal Trial Register

Verkorte titel
the TEAM-VTE study

Aandoening

Venous thromboembolism
Menstrual bleeding
Anticoagulation

Ondersteuning

Primaire sponsor: University of Leiden
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Incidence of new-onset abnormal menstrual bleeding

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

None

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Factorieel
Toewijzing:	N.v.t. / één studie arm

Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2018
Aantal proefpersonen:	210
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	15-08-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55518
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
None