NAME OF PROJECT

Risk, predictors, impact and outcome of anticoagulation-associated abnormal menstrual bleeding in patients with VTE – the TEAM-VTE study

Subcommittee: Women Health Issues

- Person responsible (Chair / Principal Investigator):
  F.A. (Erik) Klok (f.a.klok@lumc.nl) on behalf of the steering committee (Dr. F.A. Klok, Dr. K. Schreiber, Dr. K. Stach, Dr. A Delluc, Dr. M. Blondon, Dr. C. Ay and Dr. L. Bertoletti)

- Aim / Mandate of the project:
  The primary objective of the VTE-TEAM study is to assess and specify the rate of new-onset abnormal menstrual bleeding in female in their fertile age, anticoagulated for an incident case of venous thromboembolism (VTE).

- Methodology (in very brief, not more than 1 paragraph):
  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.

- Inclusion / recruitment criteria (if applicable):
  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 ≥18 years and ≤ 50 years;
  4) Confirmed symptomatic first or recurrent VTE;
  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.
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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) 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;
4) Non-compliance or inability to adhere to the follow-up visits;
5) Pregnancy or post-partum (first three months) associated VTE;
6) Active in vitro fertilization (IVF) treatment or planned IVF treatment during the study period.

- Year of starting:
  2018

- Annual report of project:
  Yes

- Year of completion (expected):
  2020

- References:
  This project grew from an earlier SSC project: