WiTEAM Project (Women International TEAM)
Women’s Health issues in thrombosis and hemostasis

- **Person responsible** (chair: Maha Othman / PI and project leader: Amparo Santamaria)

- **Design**: observational prospective, international online study providing data on women with placenta-mediated pregnancy complications and thrombophilia

- **Aim/Objective/Rationale**: The primary objective of this registry is to document prospectively the management of women with thrombophilia and previous placenta mediated complications (PMC) in a real-world situation with an unselected patient population.

- **Methodology**: observational prospective, international online registry. Only clinical routine practice will be documented. This registry has already been established in Spain by a working group of the Spanish Society of Thrombosis and Haemostasis. The goal is to expand this internationally via the ISTH support.

- **Expected timeline**:
  - Project stage/set up: First two years, patient recruitment, and inclusion in the registry. Third year, complete the recruitment, statistical analysis and report/publication of the gathered and analyzed data.
  - Launch: October 2017
  - Duration: 3 years
  - Finalization/analysis: 2020
  - Reporting: Possibility of reporting preliminary data ISTH 2019. A final report is expected 2020

- **Expected outcomes (ie. publications)**:
  - Publication type: original article

- **Description of project set/up and management, needed infrastructure and resources (summary)**:
  - **Setting**: Data will be obtained in a standardized form, registered in the database (www.teamproject.com). Institutional research and ethical approval is obtained in each center before the implementation of the study and all included participants will sign an informed consent prior to the inclusion into the study.
  - **Study Population:**
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- The plan is to include up to 2418 patients from approximately 30 sites in 10 European countries and Latin American countries and to integrate into a database.

- The sample size was estimated taking into account the prevalence of PMC and thrombophilia. Therefore, it is assumed that a maximum number of 2000 patients is needed to achieve sufficient power to observe a reduction from 7% to 4% of recurrences (alpha 0.05 and beta 0.1). The estimated enrolment period is 3 years.

- The Inclusion criteria are women aged >18 years-old with a PMC or recurrent pregnancy loss. PMCs includes PE, early-onset or severe PE, birth of a severe SGA neonate under the 5th percentile, PA leading to delivery, FD or neonatal death at over 10 weeks gestational age and less than or equal to 28 days postpartum, with normal fetal morphology having been documented by ultrasound scan or direct examination of the fetus. Recurrent pregnancy loss is defined as 3 unexplained consecutive spontaneous abortions before the 10th week of gestation, not caused by maternal anatomic or hormonal abnormalities or by paternal and maternal chromosomal causes. The study will take into account women with less than 3 miscarriages, although these will be included separately in the statistical analysis.

- Exclusion criteria were are women less than 18 years-old, women with pregnancy losses explained by infections, metabolic, anatomic, or hormonal factors.

- **Follow-up:** All participants will be followed up at least during the pregnancy period until 3 months after the delivery.

- As an observational non-interventional study following the routine clinical practice we will include all women who meet the inclusion criteria. For statistical analysis we will separate those who decide to carry prophylaxis with low molecular weight heparin during pregnancy and those that do not.

Visit 1 (V1): signed informed consent and clinical history, clinical management.

Visits 2, 3, 4 (V2, V3, V4): follow-up during pregnancy and puerperium. See chart below.
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FLOW CHART DIAGRAM

Pregnant women with known thrombophilia and PMC

V1: Informed consent, clinic history

FOLLOW UP:
V2: week 20
V3: week 37
V4: 3 months after delivery

References:


