

Confirmation of Eligibility: France Site

Screening No.

Inclusion Criteria		YES	NO
At risk for thromboembolism for <u>ONE</u> of the following reasons:			
1.	Known inherited thrombophilia (diagnosed prior to enrolment) <input type="checkbox"/> Heterozygous factor V Leiden <input type="checkbox"/> Heterozygous prothrombin gene variant <input type="checkbox"/> Protein C deficiency <input type="checkbox"/> Protein S deficiency	<input type="checkbox"/>	<input type="checkbox"/>
2.	Antepartum immobilization (strict bedrest) for ≥ 7 days at any time during pregnancy	<input type="checkbox"/>	<input type="checkbox"/>
<u>OR</u> At risk for thromboembolism for any <u>TWO</u> of the following reasons:			
3.	Pre-pregnancy BMI ≥ 30 kg/m²	<input type="checkbox"/>	<input type="checkbox"/>
4.	Smoking ≥ 5 cigarettes/day pre-pregnancy	<input type="checkbox"/>	<input type="checkbox"/>
5.	Previous clinical history of superficial vein thrombosis	<input type="checkbox"/>	<input type="checkbox"/>
6.	Pre-eclampsia (blood pressure ≥ 140 and/or 90 mmHg on at least one occasion <u>and</u> proteinuria of ≥ 0.3 grams/24 hours or ≥ 30 mg/mmol in a random urine sample)	<input type="checkbox"/>	<input type="checkbox"/>
7.	Current pregnancy ending in stillbirth (pregnancy loss > 20 weeks gestation)	<input type="checkbox"/>	<input type="checkbox"/>
8.	Emergency cesarean delivery (emergency = not previously planned)	<input type="checkbox"/>	<input type="checkbox"/>
9.	Small-for-gestational-age infant at time of delivery ($< 3^{\text{rd}}$ percentile adjusted for gestational age and sex)	<input type="checkbox"/>	<input type="checkbox"/>
10.	Postpartum infection (temperature $\geq 38.3^{\circ}\text{C}$ <u>and</u> elevated WBC <u>or</u> neutrophil count <u>or</u> positive blood cultures)	<input type="checkbox"/>	<input type="checkbox"/>
11.	Postpartum hemorrhage (> 1000 mL of blood loss, regardless of delivery mode)	<input type="checkbox"/>	<input type="checkbox"/>

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Exclusion Criteria	YES	NO
1. More than 48 hours since delivery of the placenta at the time of randomization	<input type="checkbox"/>	<input type="checkbox"/>
2. Received more than 2 doses of LMWH since delivery of the placenta	<input type="checkbox"/>	<input type="checkbox"/>
3. Need for postpartum LMWH prophylaxis or systemic anticoagulation as judged by the local investigator. May include but is not limited to the conditions below. If yes, please specify: <input type="checkbox"/> Documented history of provoked or unprovoked VTE <input type="checkbox"/> Mechanical heart valve(s) <input type="checkbox"/> Known antiphospholipid syndrome (APS) <input type="checkbox"/> Known high-risk inherited thrombophilia <input type="checkbox"/> Antithrombin deficiency <input type="checkbox"/> Homozygous factor V Leiden <input type="checkbox"/> Homozygous prothrombin gene mutation <input type="checkbox"/> Compound heterozygosity factor V Leiden and prothrombin gene mutation <input type="checkbox"/> More than 1 thrombophilia: any combination of 2 or more: factor V Leiden, prothrombin gene mutation, protein C deficiency, protein S deficiency, antithrombin deficiency <input type="checkbox"/> Other: _____	<input type="checkbox"/>	<input type="checkbox"/>
4. Need for postpartum ASA as judged by the local investigator. May include but is not limited to: <input type="checkbox"/> Documented history of myocardial infarction <input type="checkbox"/> Documented history of ischemic stroke or transient ischemic attack (TIA) <input type="checkbox"/> Other: _____	<input type="checkbox"/>	<input type="checkbox"/>
5. History of known ASA allergy	<input type="checkbox"/>	<input type="checkbox"/>
6. Documented history of a gastrointestinal ulcer	<input type="checkbox"/>	<input type="checkbox"/>
7. Known platelet count $<50 \times 10^9/L$ at any time during the current pregnancy or postpartum	<input type="checkbox"/>	<input type="checkbox"/>
8. Active bleeding at any site, excluding normal vaginal bleeding, at the time of randomization	<input type="checkbox"/>	<input type="checkbox"/>
9. Most recent known hemoglobin ≤ 70 g/L documented during the current pregnancy or postpartum	<input type="checkbox"/>	<input type="checkbox"/>
10. Known severe hypertension (SBP >200 mmHg and/or DBP >120 mmHg) during the current pregnancy or postpartum	<input type="checkbox"/>	<input type="checkbox"/>
11. Known severe hepatic dysfunction	<input type="checkbox"/>	<input type="checkbox"/>
12. Known severe renal dysfunction	<input type="checkbox"/>	<input type="checkbox"/>
13. Known severe bleeding disorder/coagulopathy	<input type="checkbox"/>	<input type="checkbox"/>
14. Known severe heart failure	<input type="checkbox"/>	<input type="checkbox"/>
15. History of a hemorrhagic cerebrovascular accident (CVA)	<input type="checkbox"/>	<input type="checkbox"/>
16. <18 years of age	<input type="checkbox"/>	<input type="checkbox"/>
17. Unable to give or refused consent	<input type="checkbox"/>	<input type="checkbox"/>

PILOT PARTUM: Eligibility

Site No.

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Subject No.

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Eligibility Criteria		YES	NO									
1.	All eligibility criteria have been met and the subject will be enrolled into the study	<input type="checkbox"/>	<input type="checkbox"/>									
2.	Version date of the consent form signed by subject:	<table border="1"> <tr> <td>D</td><td>D</td><td>M</td><td>M</td><td>M</td><td>Y</td><td>Y</td><td>Y</td><td>Y</td> </tr> </table>		D	D	M	M	M	Y	Y	Y	Y
D	D	M	M	M	Y	Y	Y	Y				

Please review with the Investigator/Co-Investigator prior to randomization:

I _____ (Investigator/Co-Investigator) confirm that I have reviewed all relevant reports, results and annotations and find the potential subject to meet all eligibility criteria. This subject may be randomized to the pilot PARTUM trial.

Investigator/Co-Investigator Signature

D	D	M	M	M	Y	Y	Y	Y
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Date