

Working Instruction SWIFT: Worksheet (Pre-)Screening



“Early factor XIII replacement in postpartum hemorrhage: multi-center, randomized, controlled, investigator-initiated trial”. Sponsor: Prof. Dr. med. Christian Haslinger

Patient ID:	Date Informed Consent signed:
	<input type="checkbox"/> short consent <input type="checkbox"/> full consent version

Inclusion criteria

	YES	NO
1. Planned vaginal delivery	<input type="checkbox"/>	<input type="checkbox"/>
2. Singleton vital pregnancy	<input type="checkbox"/>	<input type="checkbox"/>
3. Gestational age at delivery $\geq 30+0$ weeks	<input type="checkbox"/>	<input type="checkbox"/>
4. Maternal weight at admission for delivery <100 kg	<input type="checkbox"/>	<input type="checkbox"/>
5. Maternal age ≥ 18 years	<input type="checkbox"/>	<input type="checkbox"/>
If one inclusion criterion is ticked NO – the patient is NOT ALLOWED to be enrolled in the study!		

Exclusion criteria

	YES	NO
1. Antithrombotic therapy in pregnancy (therapeutic dosage) until admission for delivery (LMWH, UFH), (Note: regular inpatient antithrombotic prophylaxis is no exclusion criterion)	<input type="checkbox"/>	<input type="checkbox"/>
2. Diagnosis of preeclampsia (2021 ISSHP classification), eclampsia or HELLP syndrome	<input type="checkbox"/>	<input type="checkbox"/>
3. History of deep vein thrombosis or pulmonary embolism	<input type="checkbox"/>	<input type="checkbox"/>
4. Diagnosis of bleeding disorder or thrombophilia	<input type="checkbox"/>	<input type="checkbox"/>
5. Known thrombocytopenia during second half of pregnancy with thrombocytes < 100 G/L	<input type="checkbox"/>	<input type="checkbox"/>
6. Anemia during second half of pregnancy with Hb<80 g/L	<input type="checkbox"/>	<input type="checkbox"/>
7. Known sickle cell disease	<input type="checkbox"/>	<input type="checkbox"/>
8. malignant tumor(s)	<input type="checkbox"/>	<input type="checkbox"/>
9. participation in another study with investigational drug within the 30 days preceding and during the present study	<input type="checkbox"/>	<input type="checkbox"/>
10. inability to follow the procedures of the study, e.g. due to language problems, psychological disorders, dementia, etc. of the participant	<input type="checkbox"/>	<input type="checkbox"/>
11. known or suspected non-compliance, drug or alcohol abuse	<input type="checkbox"/>	<input type="checkbox"/>
If one exclusion criterion is ticked YES – the patient is NOT ALLOWED to be enrolled in the intervention!		

INVESTIGATOR'S SIGNATURE

Name:

Date

Signature