Appendix 3. Inclusion and Exclusion Criteria

Inclusion Criteria

I.1) Trauma patient

I.2) Patient at the obvious age of ≥ 18 years of either sex

I.3) Major bleeding or occult bleeding

I.4) Need for volume replacement therapy

I.5) Patient, who will be admitted to one of the participating hospitals

Exclusion Criteria

E.1) Solely penetrating trauma

E.2) Solely head injury

E.3) In case of ongoing severe hemodynamic instability refractory to therapy (vasopressor, volume)

E.4) Patient with inevitable lethal course as evaluated by emergency physician

E.5) Need for CPR on the scene

E.6) Deep hypothermia (<30°C)

E.7) Obviously pregnant women

E.8) Patient with known recent history of thromboembolic events within the last 6 months

E.9) Patient known to be on anticoagulant therapy

E.10) Patient with known refusal of a participation in this clinical trial

Re-check of Inclusion and Exclusion Criteria in the hospital

If it turns out that the patient is < 18 years, the patient drops out from the study and analyses immediately. To maintain the patient's safety, the fibrinogen of the patient has to be investigated after 24 h and a duplex-ultrasound has to be conducted after 7 days by the treating physician if the under aged patient dropped out before the appropriate visits (Visit 5 and Visit 7). The parent/person in custody of patient and, if applicable, the patient receives the informed consent form for information and the consequences resulting from the participation in the study.

If the CT-Scan does not confirm the bleeding at all or no additionally bleeding to a penetrating trauma or head injury, the patient will be asked to give his/her consent to continue the study per protocol.

If the pregnancy test shows that the patient is pregnant, the patient will be asked to give her consent to continue the study per protocol.

If it turns out that the patient had a thromboembolic event within the last 6 months or is on anticoagulant therapy, the patient will be asked to give his/her consent to continue the study per protocol.