Randomized trial of Factor 7 vs. placebo for spontaneous ICH

FASTEST Clinical (PI) Hotline: 1-855-429-7050 (Urgent safety / protocol related issues)

INCLUSION CRITERIA

1. Acute spontaneous ICH stroke patient
2. Able to be treated with study medication **within 2 hours** of onset or Last Known Well
3. Not on anticoagulant or structural cause of ICH
4. ICH volume of ≥ 2 cc and < 60 cc *
5. IVH Score ≤ 7 *
6. Pre-stroke mRS 0-2
7. GCS > 7
8. Age 18-80
9. Efforts to obtain informed consent per EFIC guidelines

*** ABC/2 and IVHS Calculator:**

EXCLUSION CRITERIA

1. Secondary ICH related to known causes (e.g., trauma, aneurysm, arteriovenous malformation (AVM), oral anticoagulant use (vitamin K antagonists or novel oral anticoagulants) within the past 7 days, coagulopathy, etc.)
2. IVH score > 7
3. Symptomatic thrombo-embolic or vaso-occlusive disease in past 90 days (e.g., cerebral infarction, myocardial infarction, PE, DVT, or unstable angina)
4. Clinical or EKG evidence of ST elevation consistent with acute myocardial ischemia
5. Brainstem location of hemorrhage (patients with cerebellar hemorrhage may be enrolled)
6. Known or suspected thrombocytopenia (unless current platelet count documented >50K).
7. Unfractionated heparin use with abnormal PTT
8. Low-molecular weight heparin use within the previous 24 hours
9. Recent (90 days) carotid endarterectomy or coronary or cerebrovascular angioplasty or stenting
10. Advanced or terminal illness or any other condition the investigator feels would pose a significant hazard to the patient if rFVIIa were administered
11. Recent (within 30 days) participation in any investigational drug or device trial or earlier participation in any investigational drug or device trial for which the duration of effect is expected to persist until to the time of FASTEST +enrollment
12. Planned [or high probability of] withdrawal of care or comfort care measures
13. Patient known or suspected of not being able to comply with trial protocol (e.g., due to alcoholism, drug dependency, homelessness or psychological disorder)
14. Known suspected allergy or contraindication to trial medication.
15. Previous participation in this trial (previously randomized)
16. Females of childbearing potential who are known to be pregnant or within 12 weeks post-partum and/or lactating at time of enrollment

Randomize Variables needed: ☐ Gender ☐ Race & Ethnicity ☐ NIHSS ☐ Age ☐ Weight

STUDY LABS THAT NEED TO BE COMPLETED PRIOR TO RECEIVING STUDY DRUG:

1. CT of the head with ABC/2 and IVHs score
2. EKG PI/SUB-I REVIEW for ST elevation consistent with myocardial ischemia
3. Collect SERUM TROPONIN T (blood draw MUST be prior to study drug bolus, but does NOT need to be resulted)
4. Verify Pregnancy Test (urine or serum – **IF of childbearing potential**) and confirm NOT PREGNANT

CONFIRM THE FOLLOWING STANDARD OF CARE (SOC) LABS/STUDIES HAVE BEEN COLLECTED:

☐ PT/PTT/INR (SOC)
☐ CBC with platelets (SOC)

EFIC CONSENT – use when patient cannot consent or LAR are NOT AVAILABLE

POST CONSENT or EFIC Patients:
Using **EFIC Log in real time**, document attempts made to contact LAR (see EFIC/Contacts tab); Each call/text/email attempted, regardless if answered, needs to be documented. MORE IS BETTER. Using clinical judgement and all available data, determine when to move forward with protocol implementation and drug administration.

Scan for E-Consent form

a family member with the subject can object to the study, even if not a LAR

Document Consent details. In addition, **DOCUMENT EFIC contact attempts in notes. Particularly call out attempts made post CT and prior to drug administration, as well as AFTER the drug administration.**

Primary Investigator: Name
Contact Number

Study Coordinator: Name
Contact Number

Pharmacist: Name
Contact Number

Remember to use the study drug kit with the lowest 5-digit ID Number

Scan for study drug Compounding Video

The Following Forms Must be Completed Within 6 Hours

Go To WebDCU Website:
https:webdcu.musc.edu/login.asp

Username:_____

Password:_____

1. To generate a subject ID, click 'Add New Subject', enter required info then click 'Save Record'
2. Click on the icon, at the bottom, to move to the **Subject CRF Binder**. You may need to click the 'Add New Visit' button to advance subject to the 1st visit. If not, proceed to #3
3. **Form 101 Eligibility:** Click or enter data for each of the fields required and then click 'Save Record' button.
4. Click the **[LAST STEP] 'Submit CRF'** button to enter subject, enrollment officially occurs at the time of study drug administration.

TESTS THAT NEED TO BE ORDERED FOR 24 HOURS AFTER LAST KNOWN WELL (+/- 6 HOURS):

1. **High-Sensitivity Troponin**
2. **CT of the head** – please ask the scheduler to put the wording below in the scheduling notes: "RESEARCH, FASTEST, Perform imaging according to clinical standard for patient's disease"