STUDY TEAM PHYSICIAN

PI- Kyle Walsh, MD (989)-996-0417
Coordinator – Stephanie Thomas (513)-315-4001
Back-up Coordinator – Jackie Davis (513)-403-4308
CRC Number – (513)-688-5405 or (513)-688-5406

Eligibility Criteria

Inclusion	Check if YES	Exclusion	Check if NO
Age 18-80 years with spontaneous ICH		Score of less than or equal to 7 on the Glasgow Coma Scale	
Able to treat with rFVIIa/placebo, within 120 minutes of stroke onset or last known well		Secondary ICH related to known causes *Trauma, aneurysm, arteriovenous malformation (AVM), oral anticoagulant use (vitamin K antagonists or direct oral anticoagulants) within the past 7 days, coagulopathy, etc.*	
ICH volume greater than 2 and less than or equal to 60 cc (per ABC/2 calculation)		Pre-existing disability defined as mRS 3 or greater	
IVH score less than or equal to 7		Symptomatic thrombo-embolic or vaso-occlusive disease in past 90 days *Cerebral infarction, myocardial infarction, pulmonary embolus, deep vein thrombosis, or unstable angina*	
Efforts to obtain informed consent per EFIC guidelines in the U.S or adherence to country-specific emergency research informed consent regulations		Clinical or EKG evidence of ST elevation consistent with acute myocardial ischemia	
		Brainstem location of hemorrhage *Patients with cerebellar hemorrhage may be enrolled*	
		Refusal to participate in study by patient, legal representative, or family member	
		Known or suspected thrombocytopenia *Unless current platelet count documented above 50,000 / μL.*	
FASTEST Website including ICH volume and IVH score calculator: (you do not need to log-in in order to access these links in the lower right corner of webpage) www.fasteststudy.com		Unfractionated heparin use with abnormal PTT	
		Low-molecular weight heparin use within the previous 24 hours	
		Recent carotid endarterectomy or coronary or cerebrovascular angioplasty or stenting *Within 90 days.*	
		Advanced or terminal illness or any other condition the investigator feels would pose a significant hazard to the patient if rFVIIa were administered	
		Recent 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 *Within 30 days*	
		Planned withdrawal of care or comfort care measures	
		Known or suspected of not being able to comply with trial protocol *Due to alcoholism, drug dependency, or psychological disorder*	
		Known or suspected allergy to trial medication(s), excipients, or related products	
		Contraindications to study medication	
		Previous participation in this trial *Previously randomized*	
		Currently pregnant, within 12 weeks post-partum, and/or lactating at time of enrollment	
		Patient has an Opt Out card in wallet or notation in the EMR	

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Contact the CRC on call (513-688-5405 or 513-688-5406) when there is a potential FASTEST patient

DRUG MUST BE GIVEN WITHIN 2 HOURS OF LAST KNOWN WELL

DRUG IS STORED IN SRU OMNICELL REFRIGERATOR. IT MUST BE BROUGHT TO ROOM TEMPERATURE FOR AT LEAST 10 MINUTES PRIOR TO ADMINISTRATION.

Consent by 1 of 2 methods below:

1. Paper consent before drug is preferred
2. EFIC Consent – use when patient or LAR are not available
    - Need to try to identify and obtain consent from a legally authorized representative (LAR).
    - Must have documentation of at least one attempt to contact LAR. All attempts must be kept in a log
    - If LAR gives verbal consent, document on log and have LAR sign when they arrive if possible
    - If consent cannot be obtained/ LAR not able to be located and drug start is pending, stroke team can authorize drug start. Continued efforts to contact LAR should be done and they should be consented as soon as possible.
      **a family member with the subject can object to the study, even if not a LAR!*

Tests that need to be completed prior to receiving study drug:

_____ ORDER High Sensitivity Troponin (blood MUST be drawn prior to bolus, but does NOT need to result prior to bolus)
_____REVIEW SOC EKG – PI/SUB I - If ST elevation consistent with myocardial ischemia, do not enroll.

Drug Order Set in EPIC:

IDS 2914-21 Recombinant Factor VIIa Versus Placebo (FASTEST)

Tests that need to be ordered for 24 hours after Last Known Well (+/- 6 hours):

_____ ORDER High Sensitivity Troponin

_____ ORDER CT Head– please ask the scheduler to put the wording below in the scheduling notes:
"RESEARCH, Walsh-2020-0255-001-FASTEST, Perform imaging according to clinical standard for patient's disease"

Drug Compounding Video:

https://dcu.musc.edu/campus/ProjectTraining/FASTESTPharmacyCompounding.mp4