Recombinant Factor VIIa (rFVIIa) for Hemorrhagic Stroke Trial

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 80 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Patients aged 18-80 years, inclusive 2. Patients with spontaneous ICH 3. Able to treat with study medication (rFVIIa/placebo) within 120 minutes of stroke onset or last known well 4. Efforts to obtain informed consent per EFIC guidelines (U.S.) or adherence to country-specific emergency research informed consent regulations (Canada, Germany, Spain, U.K., Japan)

Exclusion Criteria:

1. Score of 3 to 7 on the Glasgow Coma Scale 2. 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.) 3. ICH volume \< 2 cc or ≥ 60 cc 4. Blood filling 2/3 or more of one lateral ventricle of the brain, OR, blood filling at least 1/3 of both lateral ventricles. 5. Pre-existing disability (mRS \> 2) 6. Symptomatic thrombotic or vaso-occlusive disease in past 90 days (e.g., cerebral infarction, myocardial infarction, pulmonary embolus, deep vein thrombosis, or unstable angina) 7. Clinical or EKG evidence of ST elevation consistent with acute myocardial ischemia 8. Brainstem location of hemorrhage (patients with cerebellar hemorrhage may be enrolled) 9. Refusal to participate in study by patient, legal representative, or family member 10. Known or suspected thrombocytopenia (unless current platelet count documented above 50,000/μL) 11. Unfractionated heparin use with abnormal PTT 12. Pro-coagulant drugs within 24 hours prior to patient enrollment into the FASTEST trial (example, tranexamic acid or aminocaproic acid) 13. Low-molecular weight heparin use within the previous 24 hours 14. Recent (within 90 days) carotid endarterectomy or coronary or cerebrovascular angioplasty or stenting 15. Advanced or terminal illness or any other condition the investigator feels would pose a significant hazard to the patient if rFVIIa were administered 16. 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 17. Planned withdrawal of care or comfort care measures 18. Patient known or suspected of not being able to comply with trial protocol (e.g., due to alcoholism, drug dependency, or psychological disorder) 19. Known or suspected allergy to trial medication(s), excipients, or related products 20. Contraindications to study medication 21. Previous participation in this trial (previously randomized) 22. Females of childbearing potential who are known to be pregnant or within 12 weeks post-partum and/or lactating at time of enrollment

Conditions & Interventions

Interventions:
BIOLOGICAL: Recombinant Activated Factor VII (rFVIIa), BIOLOGICAL: Placebo
Conditions:
Intracerebral Hemorrhage

More Information

Contact(s): Joseph Broderick, MD - joseph.broderick@uc.edu
Principal Investigator: Rivet, Dennis, James
Phase: PHASE3
IRB
Number: HM20020430
System ID: NCT03496883
