Strategy for Improving Stroke Treatment Response

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Age 18 years and older 2. Suspected anterior circulation acute ischemic stroke 3. NIH Stroke Scale score ≥4 prior to randomization a. The participant must have a clearly disabling deficit if NIHSS is 4-5. 4. Favorable baseline neuroimaging consisting of all of the following: a. ASPECTS of 6 or more on CT (or ASPECTS of ≥7 on MRI) b. Favorable perfusion imaging on CT perfusion (CTP)/MR-perfusion weighted imaging (PWI) consisting of all of the following: i. Mismatch ratio of penumbra: core \>1.2 ii. Mismatch volume \>10 cc iii. Core \<70 cc 5. Able to receive assigned study drug within 4.5 to 24 hours of stroke onset or last known well. 6. Able to receive assigned study drug within 120 minutes of qualifying perfusion imaging. * 7. Informed consent for the study participation obtained from participant or their legally authorized representatives. * Study drug administration is encouraged within 90 minutes after qualifying perfusion image but is allowed up to 120 minutes. After 120 minutes, another perfusion image to ensure that inclusion criteria are met is required.

Exclusion Criteria:

1. Received endovascular treatment with clot engagement. 1. Patients who undergo groin puncture but clot engagement is not attempted due to spontaneous distal migration are permitted to be enrolled in the trial if all other eligibility criteria are met. 2. Patients who undergo groin puncture but clot is not engaged due to reasons other than spontaneous distal migration are NOT permitted. 2. Received or planned to receive intravenous thrombolysis. 3. Pre-stroke modified Rankin score \>2. 4. Previous treatment with TS23 or known previous allergy to antibody therapy. 5. Known pregnancy, women who are breastfeeding or plan to breastfeed within 3 months of receiving TS23 or have a positive urine or serum pregnancy test for women of childbearing potential. 6. Known previous stroke in the past 90 days. 7. Known previous intracranial hemorrhage, intracranial neoplasm, subarachnoid hemorrhage, or arterial venous malformation. 8. Known active diagnosis of intracranial neoplasm. 9. Clinical presentation suggestive of a subarachnoid hemorrhage, even if initial CT scan was normal. 10. Surgery or biopsy of parenchymal organ in the past 30 days. 11. Known trauma with internal injuries or persistent ulcerative wounds in the past 30 days. 12. Severe head trauma in the past 90 days. 13. Persistent systolic blood pressure \>180mmHg or diastolic blood pressure \>105mmHg despite best medical management. 14. Serious systemic hemorrhage in the past 30 days. 15. Known hereditary or acquired hemorrhagic diathesis, coagulation factor deficiency, or oral anticoagulant therapy with International Normalized Ratio (INR) \>1.7. 16. Platelets \<100,000/mm3. 17. Hematocrit \<25 %. 18. Elevated aPTT above laboratory upper limit of normal. 19. Creatinine \> 4 mg/dl, or patients receiving renal dialysis, regardless of creatinine. 20. Received the following within the previous 24 hours: 1. If patient received unfractionated heparin within the last 24 hours, the patient must have an aPTT within normal range prior to enrollment. 2. Low molecular weight heparins such as Dalteparin, enoxaparin, tinzaparin in full dose within the previous 24 hours. 21. Received Factor Xa inhibitors (such as Fondaparinux, apixaban or rivaroxaban) within the past 48 hours. 22. Received direct thrombin inhibitors (e.g., argatroban, dabigatran, bivalirudin, desirudin, lepirudin) within 48 hours. 23. Received glycoprotein IIb/IIIa inhibitors within the past 14 days. 24. Known pre-existing neurological or psychiatric disease which would confound the neurological/functional evaluations. 25. Current participation in another research drug treatment protocol (i.e., participants could not start another experimental agent until after 90 days). 26. Concurrent acute myocardial infarction, pulmonary embolism, deep venous thrombosis or other thrombotic event that requires anticoagulation or anti-platelet treatment.

Conditions & Interventions

Interventions:
BIOLOGICAL: TS23
Conditions:
Ischemic Stroke

More Information

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