Efficacy and Safety Study of GM602 in Patients With Acute Middle Cerebral Artery Ischemic Stroke Within 18 Hours (GMAIS)

This study is currently recruiting participants.

Verified May 2013 by Genervon Biopharmaceuticals, LLC

Sponsor:
Genervon Biopharmaceuticals, LLC

Collaborators:
University of California, Los Angeles
Huntington Hospital
Hoag Memorial Hospital Presbyterian
Columbia University
California Pacific Medical Center Research Institute
Erlanger Healthcare System
Sarasota Memorial Hospital
University of Louisville

Information provided by (Responsible Party):
Genervon Biopharmaceuticals, LLC

ClinicalTrials.gov Identifier:
NCT01221246

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History of Changes

Purpose

The purpose of this research study is to determine whether the investigational drug GM602, is effective and safe in the treatment of ischemic stroke (strokes caused by a blood clot blocking the flow of blood through one, or more of the blood vessels supplying the brain) when administered up to 18 hours after symptoms begin.

Condition	Intervention	Phase
Stroke	Drug: GM602 Drug: Matching Placebo (Bacteriostatic Saline) for GM602	Phase 2

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: A Phase 2 Double Blinded, Randomized, Placebo Controlled Dose Escalation Study to Evaluate the Efficacy and the Safety of GM602 in Patients With Acute Middle Cerebral Artery Ischemic Stroke Within an 18-hour Treatment Window

Further study details as provided by Genervon Biopharmaceuticals, LLC:

Primary Outcome Measures:

- Functional Outcome as measured by the difference in percent change in NIHSS from baseline to 90 days in patients treated with GM602 within 18 hours compared to treated with placebo as primary efficacy endpoint [Time Frame: Day 90] [Designated as safety issue: No]

  NIH Stroke Scale is a standardized neurological examination intended to describe the neurological deficits found in large groups of stroke patients participating in treatment trials. Percent change from baseline in NIHSS is calculated and compared.

- Compare the safety and tolerability of GM602 with placebo in a population of patients with moderate to severe impairment following acute

ischemic stroke as primary safety endpoint. [Time Frame: Day 90] [Designated as safety issue: Yes]

Safety and tolerability issues include: adverse events, hemorrhage, neurological deterioration, seizure, respiratory compromise

Secondary Outcome Measures:

- Functional Outcome as measured by the difference in percent change in NIHSS from baseline to 30 days in patients treated with GM602 compared to treated with placebo [Time Frame: Day 30] [Designated as safety issue: No]
- Functional Outcome as measured by the difference in percent change in Barthel Index (BI) from baseline to 90 days in patients treated with GM602 compared to treated with placebo [Time Frame: Day 90] [Designated as safety issue: No]

  The Barthel Index is measured using both historical and direct observational information. It measures self-care and mobility and will help define the degree of residual disability. Percent change from baseline in BI is calculated.

- Functional Outcome as measured by the difference in percent change in Barthel Index (BI) from baseline to 30 days in patients treated with GM602 compared to treated with placebo [Time Frame: Day 30] [Designated as safety issue: No]
- Efficacy as measured by Proportion of patients treated with any active dose of GM602 compared with placebo at each mRS level at 90 days [Time Frame: Day 90] [Designated as safety issue: No]

  The Modified Rankin Scale is the most commonly used global scale. It is a simple overall measure of independence that allows comparisons between patients with different kinds of neurologic deficits, and it also helps to evaluate recovery.The best possible score is 0; the worst is 5. Number of patients at each mRS level are summarized in a table.

- Efficacy as measured by Proportion of patients treated with any active dose of GM602 compared with placebo at each mRS level at 30 days [Time Frame: Day 30] [Designated as safety issue: No]
- Secondary safety endpoint as measured by all cause mortality data through 3 months for patients treated with GM602 compared with placebo [Time Frame: Day 90] [Designated as safety issue: Yes]

Estimated Enrollment:	36
Study Start Date:	February 2011
Estimated Study Completion Date:	September 2014
Estimated Primary Completion Date:	March 2014 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Active Comparator: GM602 First 9 moderate patients (either co-treated or not co-treated) will be randomized to receive 320 mg/dose of GM602 or placebo in a 2:1 ratio, then the next 9 moderate patients (either co-treated or not co-treated) will be randomized to receive 480 mg/dose of GM602 or placebo in a 2:1 ratio. Concurrently, 18 severe patients will be randomized in the same manner. Total 12 moderate and 12 severe patients will receive GM602.	Drug: GM602 First 9 moderate patients (either co-treated or not co-treated) will be randomized to receive 320 mg/dose of GM602 or placebo in a 2:1 ratio, then the next 9 moderate patients (either co-treated or not co-treated) will be randomized to receive 480 mg/dose of GM602 or placebo in a 2:1 ratio. Concurrently, 18 severe patients will be randomized in the same manner. Total 12 moderate and 12 severe patients will receive GM602.
Placebo Comparator: Matching Placebo (Bacteriostatic Saline) First 9 moderate patients (either co-treated or not co-treated) will be randomized to receive 320 mg/dose of GM602 or placebo in a 2:1 ratio; then the next 9 moderate patients (either co-treated or not co-treated) will be randomized to receive 480 mg/dose of GM602 or placebo in a 2:1 ratio. Concurrently, 18 severe patients will be randomized in the same manner. Total 6 moderate and 6 severe patients receive Placebo.	Drug: Matching Placebo (Bacteriostatic Saline) for GM602 First 9 moderate patients (either co-treated or not co-treated) will be randomized to receive 320 mg/dose of GM602 or placebo in a 2:1 ratio, then the next 9 moderate patients (either co-treated or not co-treated) will be randomized to receive 480 mg/dose of GM602 or placebo in a 2:1 ratio. Concurrently, 18 severe patients will be randomized in the same manner. Total 6 moderate and 6 severe patients will receive placebo.

Detailed Description:

Stroke is a serious and life threatening disease. About 85% of all strokes are ischemic, caused by a blood clot or plaque that blocks a blood vessel in the brain. The thrombolytic drug tissue plasminogen activator (tPA) is the only early treatment for acute ischemic stroke approved by the FDA. Treatment with tPA must be administered within three hours of the stroke onset. Furthermore, tPA treatment carries a recognized risk of bleeding in the brain. GM602 is an investigational drug that may act as a neuroprotectant in patients who have had a stroke. It is thought to stop cell death and reduce inflammation in the injured area of the brain. This study is designed to evaluate the safety and efficacy of GM602 administered intravenously to patients in three consecutive daily doses of 320 mg/dose or 480 mg/dose, the initial dose administered within 18 hours after onset of acute ischemic stroke in the Middle Cerebral artery region.

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- > 18 years old
- Be eligible for MRI or CT scan
- Have suffered acute ischemic stroke in the middle cerebral artery (MCA) distribution, as verified by the Screening DWI abnormality and Screening PWI abnormality
- Have NIH Stroke Scale (NIHSS) score total score of 9-20 inclusive at screening
- Have suffered acute ischemic stroke within 18 hours
- Have been functionally independent with a Modified Rankin Score (mRS) of 0 or 1 prior to suffering stroke
- Patients who received tPA or FDA approved mechanical device can also enroll
- completed informed consent form

Exclusion Criteria:

- Have history of stroke in the past 3 months
- Cannot be evaluated using MRI/CT
- Have stroke of the brainstem or cerebellum
- Have clinical presentation consistent with acute MI by EKG criteria (STEMI) at screening
- Have hemorrhage revealed by CT or MRI scan
- Have > 1/3 MCA territory HYPER intensity as seen on MRI OR >1/3 MCA territory HYPO intensity as seen on CT
- Have blood sugar level >400 mg/DL or<50 mg/dL
- Have kidney disease, creatinine > 2.0
- Have had recent (within 90 days) serious head trauma or head trauma with loss of consciousness
- Have any prior history of seizure
- Have clinically relevant pre-existing neurological deficit (Historical Rankin score ≥ 2)
- Have any other known clinically significant medical disorder (cardiovascular, hepatic, renal, endocrine, respiratory, immunological, cancer, AIDS)
- Life expectancy of less than 6 months due to comorbid conditions
- Women of child bearing potential who are pregnant or breast-feeding or unable to practice birth control during the study period
- Have participated in any other trial of an investigational agent within 90 days prior to screening
- Informed consent cannot be obtained
- Unable to participate in study visits

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01221246

Locations

United States, California

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Sponsors and Collaborators

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More Information

No publications provided

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Keywords provided by Genervon Biopharmaceuticals, LLC:
Acute Middle Cerebral Artery Ischemic Stroke within 18 hours

Additional relevant MeSH terms:

Stroke	Nervous System Diseases
Cerebral Infarction	Vascular Diseases
Cerebrovascular Disorders	Cardiovascular Diseases
Brain Diseases	Brain Infarction
Central Nervous System Diseases	Brain Ischemia

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