

Treatment of Acute Ischemic Stroke (ReMEDy2 Trial)

NCT05065216

Status	RECRUITING
Phase	Phase 2, Phase 3
Sponsor	DiaMedica Therapeutics Inc
Enrollment	728 participants

Key Eligibility Criteria

Inclusion (5)

- Participant is between 18 and 90 years of age inclusive.
- Participant weight is 40 kg to 166 kg inclusive.
- Participant to be randomized and treatment initiated within 24 hours of last known normal/AIS stroke onset.
- Participant has NIHSS e5 and d15 at approximately the time of randomization. This criterion also applies to participants who meet the following conditions:
 - The participant initially presents with an NIHSS score below 5 but clinically worsens, including cases of progressing stroke / stroke-in-evolution, resulting in a subsequent persistent NIHSS score of e5 and d15; and

Exclusion (37)

- Participant had a pre-morbid mRS score of 0 to 1 (mRS score prior to AIS) as stated by participant or participant's representative.
- If participant has received fibrinolytic treatment for AIS within 4.5 hours of last known normal/AIS stroke onset and at least 6 hours after completing fibrinolytic treatment, and the participant meets all of the following criteria:
 - Participant's initial NIHSS score prior to fibrinolytics was d15; and
 - At least six hours after fibrinolytics, the participant has NIHSS score of e5 and d15 with a persistent deficit; and
 - The participant's NIHSS score showed less than a 4-point improvement, or worsened, after receiving fibrinolytics; and
- ... and 32 more (see full listing online)

Locations (60 total)

Gulf Health Hospitals d/b/a Thomas Hospital, Fairhope, Alabama, United States
USC Arcadia Hospital, Arcadia, California, United States
Glendale Adventist Medical Center d/b/a Adventist Health Glendale, Glendale, California, United States
... and 57 more locations

<https://clinicaltrials.gov/study/NCT05065216>

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