

Add-on benefit of cerebrolysin to acute stroke patients given recombinant tissue plasminogen activator

Submission date 19/06/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/07/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 03/07/2025	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Stroke is the third leading cause of death and disability in the Philippines. This study aims to determine if cerebrolysin has an add-on benefit to patients receiving thrombolysis, which involves the use of drugs to break down and dissolve blood clots.

Who can participate?

Patients 18 years old and above diagnosed with moderate to severe stroke who would receive thrombolysis therapy, admitted at Baguio General Hospital and Medical Center

What does the study involve?

Participants are randomly allocated to be treated with either cerebrolysin or a placebo.

What are the possible benefits and risks of participating?

Benefits include improved motor and cognitive deficits of stroke patients and decreased brain bleeding. Risks include fever and allergic reactions.

Where is the study run from?

Baguio General Hospital and Medical Center and East Avenue Medical Center (Philippines)

When is the study starting and how long is it expected to run for?

May 2024 to August 2025

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

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Contact information

Type(s)

Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

BGHMC-REC-2023-22

Study information

Scientific Title

Multi-center trial on the efficacy of cerebrolysin in acute ischemic stroke after intravenous thrombolysis

Acronym

CERECAP

Study objectives

Among thrombolitized patients with moderate to severe acute ischemic stroke (NIHSS >10) does cerebrolysin improve neurologic outcomes?

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 24/05/2024, BGHMC Research Ethics Committee (BGH compound Gov Pack Road, Baguio City, 2600, Philippines; +63 (0)74 661 7910; rec@bghmc.doh.gov.ph), ref: BGHMC REC 2023-22

Study design

Randomized open-label multi-center prospective cohort study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Efficacy

Participant information sheet

Not available

Health condition(s) or problem(s) studied

Acute ischemic stroke after intravenous thrombolysis

Interventions

Patients will be randomized using the research randomizer to either the treatment group or the control group. The research randomizer (randomizer.org) is a free online software used to generate random numbers or assign participants to different groups. Patients randomized to the treatment group will be given Cerebrolysin at a dose of 30 cc IV infusion for 15 minutes for 21 days by the stroke nurse in charge. The initial dose will be given within 1 hour after thrombolysis in a separate IV line. The drug should be immediately given once opened. The infusion set will be changed daily to prevent infection. The venous line must be rinsed before and after the application with plain normal saline solution (NSS). If, however, the patient can already be discharged, Cerebrolysin infusion will be continued at home and will be given by a nurse trained to give the drug. The control group will receive a placebo (plain NSS).

Intervention Type

Drug

Pharmaceutical study type(s)

Not Applicable

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Cerebrolysin

Primary outcome measure

Degree of independence or disability measured using the Modified Rankin Scale (MRS) at discharge and 3 months

Secondary outcome measures

1. Symptomatic ICH assessed using CT scan at baseline (admission), 24 hours and 5 days
2. Degree of cognitive dysfunction measured using the Montreal Cognitive Assessment (MoCA) test at 3 months
3. Degree of stroke severity measured using the National Institutes of Health Stroke Scale, or NIH Stroke Scale (NIHSS) at baseline (admission), 24 hours, discharge and 3 months

Overall study start date

23/05/2024

Completion date

22/08/2025

Eligibility

Key inclusion criteria

1. >18 years old
2. Having an acute ischemic stroke within 4.5 hours post-ictus, moderate to severe stroke with NIHSS 10-25 on admission
3. Meets criteria for intravenous thrombolysis

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

100 Years

Sex

Both

Target number of participants

60

Key exclusion criteria

1. Hemorrhagic strokes on baseline CT scan
2. History of hepatic failure
3. History of chronic kidney disease (creatinine clearance <30)
4. Stroke mimickers

Date of first enrolment

24/05/2024

Date of final enrolment

22/05/2025

Locations

Countries of recruitment

Philippines

Study participating centre

Baguio General Hospital and Medical Center

Gov Pack Road

Baguio City

Philippines

2600

Study participating centre

East Avenue Medical Center

East Avenue

Quezon City

Philippines

1100

Sponsor information

Organisation

Baguio General Hospital and Medical Center

Sponsor details

Gov Pack Road

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Sponsor type

Hospital/treatment centre

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

22/05/2027

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date