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

Submission date 19/06/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 03/07/2025	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 03/07/2025	**Condition category** Circulatory System	[_] Individual participant data [X] 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?
Peter Allan A. Quitasol, peterallanquitasol@gmail.com

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 thrombolyzed 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

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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