

Triple therapy to boost stroke recovery in Azerbaijan: combining brain stimulation, medication, and physiotherapy

Submission date 30/01/2025	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 13/02/2025	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 12/02/2025	Condition category Circulatory System	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

This research will study the effectiveness of cerebrolysin in combination with physical methods of treatment, including transcranial direct current stimulation (tDCS), kinesiotherapy, and massage, in the rehabilitation of patients with cerebral stroke.

Who can participate?

Patients aged between 18 and 85 years old with acute ischemic stroke in the early recovery period (90-180 days) and late (from 6 months to a year)

What does the study involve?

The investigators hypothesize that the triple therapy concept in this study (cerebrolysin plus tDCS plus standardized physiotherapy) will be superior in improving the patient's motor skills and quality of life after stroke compared to traditional physiotherapy plus tDCS alone.

What are the possible benefits and risks of participating?

Benefits and risks not provided at registration

Where is the study run from?

The Azerbaijan Scientific Research Institute of Medical Rehabilitation

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

March 2024 to March 2026

Who is funding the study?

The Azerbaijan Scientific Research Institute of Medical Rehabilitation

Who is the main contact?

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Contact information

Type(s)

Public, Scientific, Principal investigator

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Additional identifiers**Study information****Scientific Title**

CINEMA study - cerebrolysin neuro modulation Azerbaijan

Acronym

CINEMA

Study objectives

The investigators hypothesize that the innovative triple therapy concept in this study (cerebrolysin plus transcranial direct current stimulation [tDCS] plus standardized physiotherapy) will be superior in improving the patient's motor skills and quality of life after stroke compared to traditional physiotherapy plus tDCS alone.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 23/09/2024, Ethics Committee of Azerbaijan Medical University (Samad Vurghun, Baku, AZ1022, Azerbaijan; +994125973898; info@amu.edu.az), ref: 35

Primary study design

Interventional

Study design

Single-centre interventional randomized open-label study

Study type(s)

Safety, Efficacy

Health condition(s) or problem(s) studied

To study the effectiveness of the use of cerebrolysin in combination with physical methods of treatment (direct current stimulation, kinesitherapy, massage) in the rehabilitation of patients with cerebral stroke.

Interventions

This is a single-centre interventional randomised open-label study design:

The study will involve 60 patients with cerebral stroke (CS) in the early (from 3 to 6 months) and late (from 6 months to a year) recovery periods of the disease. Patients will be divided into 2 groups.

1. Patients in group I (main) will receive injections of cerebrolysin - 30 ml diluted in 100 ml of NaCl solution, intravenously, by drop infusion (14 days). On the same day, patients will receive transcranial direct current stimulation (tDCS) kinesiotherapy (proprioceptive neuromuscular facilitation (PNF), constraint-induced movement (Ci) therapy) and massage.

2. Patients of group II (control, comparison group) will receive only tDCS kinesiotherapy and massage.

Methods of kinesitherapy (task-oriented approach):

1. Treatment by constraint-induced movement, Ci-therapy.
2. Method of proprioceptive muscle facilitation - PNF.

Intervention Type

Mixed

Primary outcome(s)

Functional activity of the upper limbs is measured using the Action Research Arm Test (ARAT) on the 14th day after the start of treatment

Key secondary outcome(s)

The following secondary outcome measures are assessed on day 15:

1. The severity of neurological deficit measured using the NIH Stroke Scale/Score (NIHSS) scale
2. Daily life activity measured using the Barthel scale (and Rankin scale)
3. Cognitive functions measured using the Mini-Mental State Examination (MMSE) scale (or Functional Independence Measure (FIM), Montreal Cognitive Assessment (MoCA))
4. Functional activity of the upper limbs measured using the ARAT
5. Electrical activity of the muscles measured using electromyography (EMG)

Completion date

01/03/2026

Eligibility

Key inclusion criteria

1. Ischemic stroke patients
2. Non-transient arm paresis
3. Aged 18-85
4. Intact cortico-spinal tract
5. Baseline NIHSS above 8.

Participant type(s)

Health professional

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

85 Years

Sex

All

Key exclusion criteria

1. Progressive or unstable stroke
2. Preexisting or active major neurological or psychiatric disease
3. History of significant alcohol or drug abuse within the previous 3 years
4. Advanced liver, kidney, cardiac, or pulmonary disease
5. Terminal medical diagnosis with an expected survival of <1 year
6. Substantial decrease in alertness at the time of randomization
7. Any condition that would represent a contraindication for cerebrolysin administration, including allergy
8. Pregnancy or lactation
9. Participation in another therapeutic study of stroke or stroke recovery

Date of first enrolment

01/03/2024

Date of final enrolment

01/03/2026

Locations

Countries of recruitment

Azerbaijan

Study participating centre

Azerbaijan Scientific Research Institute of Medical Rehabilitation

AZ1073, 103 Mikail Mushfig

Baku

Azerbaijan

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Sponsor information

Organisation

Azerbaijan Medical University

ROR

<https://ror.org/016a0n751>

Funder(s)**Funder type**

University/education

Funder Name

Azerbaijan Scientific Research Institute of Medical Rehabilitation

Results and Publications**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be available upon request from Mrs Huseynova Sadagat, hsadagat@gmail.com, huseynova-sadagat@rambler.ru

IPD sharing plan summary

Available on request