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

Submission date
30/01/2025

Recruitment status
Recruiting

Registration date
13/02/2025

Overall study status
Ongoing

Last Edited
12/02/2025

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] 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), kinesitherapy, 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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

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

Study design
Single-centre interventional randomized open-label study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
University/medical school/dental school

Study type(s)
Safety, Efficacy

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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

Secondary outcome measures
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)

Overall study start date
01/03/2024

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

Age group
Mixed

Lower age limit
18 Years

Upper age limit
85 Years

Sex
Both

Target number of participants
60

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 <l 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
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Sponsor information

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Azerbaijan Medical University

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Funder(s)

Funder type

University/education

Funder Name
Azerbaijan Scientific Research Institute of Medical Rehabilitation

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal.

Intention to publish date
31/10/2026

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