

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

The efficacy of Cerebrolysin in the treatment of acute ischemic stroke

Protocol summary

Summary

Aim: to evaluate the efficacy of Cerebrolysin and the rate of nerve protection which arise by this drug in patients with acute ischemic brain attack. Method: 100 patients, aged 45-85 years, with cerebral ischemic attack will participate in the trial. They will be selected during the first 12 hours after symptoms of acute stroke. They should take routine treatment. They will be allocated to Cerebrolysin or placebo groups randomly. Intervention group will take Cerebrolysin 30 ml per day for 5 days in the first week and 10 ml per day for 5 days in the second, third and fourth weeks. Control group will take placebo in the same dose and duration. We quantify the improved dynamic time based on depletion neurologic finding and tendency to create and to help expedite the progress of recovery criteria: PGS (Patient Global Satisfaction Score), MRS (Modified Rankin Scale), CGIS (Clinical Global Impression Scale), Barthel Index, MMSE (Mini-Mental State Exam), NIHSS (National Institutes of Health Stroke Scale) in both groups during the 30-day evaluation period. Criteria of neurologic symptoms shall be evaluated during the injection sequence with specific and defined information obtained in the form of specific projects. Neurologic level and improved performance status will be evaluated before and 3 or 4, 7, 15 and 30 days after the treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138803272042N1**
Registration date: **2009-08-29, 1388/06/07**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2009-08-29, 1388/06/07

Registrant information

Name

kurosh Gharagozli

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 7243

Email address

gharagoz@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Cobel Darou company on behalf of Ebewe Pharma

Expected recruitment start date

2009-08-23, 1388/06/01

Expected recruitment end date

2010-08-23, 1389/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of Cerebrolysin in the treatment of acute ischemic stroke

Public title

The efficacy of Cerebrolysin in the treatment of acute ischemic stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients aged 45 to 85 years, the occurrence of acute cerebral ischemic attack (embolic or thrombotic), hospitalization during 12 hours of first symptoms of stroke, systolic blood pressure less than 200 and diastolic less than 100 mmHg Exclusion Criteria:

recovery of neurologic symptoms after 4 hours of attack, hemorrhagic stroke or the occurrence of stroke in vertebrobasilar system with blood pressure $\geq 200/100$ mmHg, seizures, Papilledema or rising intracranial pressure (RICP), neck stiffness or symptoms of brain stimulation, the condition of consciousness stupor and coma (GCS ≤ 6), acute myocardial infarction, National Institutes of Health Stroke Scale (NIHSS) less than 7 and more than 24, hepatic or renal failure - heart failure, dementia initial appearance, acute infectious disease, doubt the Involvement in subsequent brain area (posterior circulation), pregnant women, symptoms of progressive neurologic defects, patients who are in other trials, patients received piracetam or calcium channel blockers (CCB), Patients who received r-TPA treatment during first 4 hours of symptoms

Age

From **45 years** old to **85 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences - next to the Taleghani Hospital - Evin

City

Tehran

Postal code**Approval date**

2008-03-16, 1386/12/26

Ethics committee reference number

51

Health conditions studied**1****Description of health condition studied**

Cerebral infarction

ICD-10 code

I63

ICD-10 code description

Cerebral infarction

Primary outcomes**1****Description**

Clinical evaluation of motor ability (speech and motor ability of patients)

Timepoint

daily

Method of measurement

MRS (Modified Rankin Scale), NIHSS (National Institutes of Health Stroke Scale)

Secondary outcomes**1****Description**

Improvement in the understanding of patients during the treatment

Timepoint

On days 3, 7, 15 and 30

Method of measurement

Assessment of CGIS (Clinical Global Impression Scale), PGS (Patient Global Satisfaction Score) and MMSE (Mini-Mental State Exam) by neurologist

Intervention groups**1****Description**

Intervention: Cerebrolysin (30 mg for first 5 days during the first week and 10 mg for first 5 days in the second, third and fourth weeks) adding to routine therapy

Category

Treatment - Drugs

2**Description**

Control: placebo in the same dose of the intervention group

Category

empty

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman Hakim Hospital

Full name of responsible person

Dr Kurosh Gharagozli

Street address

Kamali St.- South Kargar St.

City

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2

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Dr Nahid Beladimoghadam

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Madani St.

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3

Recruitment center

Name of recruitment center

Shohada Hospital

Full name of responsible person

Dr Abulfazle Hemati

Street address

Ghods Sq.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy, Shahid Beheshti University of
Medical Sciences

Full name of responsible person

Dr Mohammad Rahmati

Street address

Next Taleghani Hospital - Evin

City

Tehran

Grant name

Grant code / Reference number

**Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Research Deputy, Shahid Beheshti University of Medical
Sciences

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

2

Sponsor

Name of organization / entity

Cobel Darou

Full name of responsible person

Memarian

Street address

39 Alvand Ave.

City

Tehran

Grant name

Grant code / Reference number

**Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Cobel Darou

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr kurosh Gharagozli

Position

Associate Professor of Neurology

Other areas of specialty/work

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Position

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Other areas of specialty/work**Street address**

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Fax**Email****Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty