Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

The effect of cerebrolysin versus placebo on improvement of patients with acute ischemic stroke: a double blinded randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of cerebrolysin versus placebo on improvement of patients with acute ischemic stroke. Design: A double blinded randomized clinical trial. Setting and conduct: All eligible patients with acute ischemic stroke who will refer to clinic of Farshchian Hospital will be enrolled in to the trial. Inclusion criteria: (a) having ischemic stroke; (b) age of 40 to 85 years; (c) referring the patient within less than 24 hours after stroke. Exclusion criteria: (a) being in coma; (b) having systolic blood pressure above 240 mmHg or diastolic blood pressure above 120 mmHg; (c) history of myocardial infarction or heart failure; (d) history of renal failure; (e) history of liver failure; (f) having severe dementia. Intervention: Routine treatment of ischemic stroke plus intravenous infusion of cerebrolysin 10 ml in 100 ml normal saline daily for 7 days. Control: Routine treatment of ischemic stroke plus intravenous infusion of 100 ml normal saline alone daily for 7 days. Primary outcome: measuring motor function using Canadian Stroke Scale before intervention and 3 and 7 days after intervention. Secondary outcome: (a) measuring motor function using Madified Ranking Scale one month after intervention; (b) measuring motor function using Bartel Index one month after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201406169014N36**
Registration date: **2014-06-23, 1393/04/02**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-06-23, 1393/04/02

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2013-07-23, 1392/05/01

Expected recruitment end date

2014-06-21, 1393/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cerebrolysin versus placebo on improvement of patients with acute ischemic stroke: a double blinded randomized clinical trial

Public title

The effect of cerebrolysin versus placebo on improvement of patients with acute ischemic stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (a) having ischemic stroke; (b) age of

40 to 85 years; (c) referring the patient within less than 24 hours after stroke. Exclusion criteria: (a) being in coma; (b) having systolic blood pressure above 240 mmHg or diastolic blood pressure above 120 mmHg; (c) history of myocardial infarction or heart failure; (d) history of renal failure; (e) history of liver failure; (f) having severe dementia.

Age
From **40 years** old to **85 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **122**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Randomization: A systematic random allocation method is used so that the patients who referred to the first specialist were assigned to the intervention group and the patients who referred to the second specialist were assigned to the control group. Blinding: All patients received the same intravenous treatment with different context. Thus they were unaware of the type of intervention. In addition, the physician who examined the patients was not aware of the intervention. Therefore, the trial was run as double blinded.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethic Committee of Hamadan University of Medical Sciences

Street address
Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City
Hamadan

Postal code
6517838695

Approval date
2014-05-17, 1393/02/27

Ethics committee reference number
P/16/35/9/705

Health conditions studied

1

Description of health condition studied
Ichemic stroke

ICD-10 code
I63

ICD-10 code description
cerebral infarction

Primary outcomes

1

Description
measuring motor function

Timepoint
before intervention and 3 and 7 days after intervention

Method of measurement
using Canadian Stroke Scale

Secondary outcomes

1

Description
measuring motor function

Timepoint
one month after intervention

Method of measurement
using Madified Ranking Scale

2

Description
measuring motor function

Timepoint
one month after intervention

Method of measurement
using Bartel Index

Intervention groups

1

Description
Routine treatment of ischemic stroke plus intravenous infusion of cerebrolysin 10 ml in 100 ml normal saline daily for 7 days

Category
Treatment - Drugs

2

Description
Routine treatment of ischemic stroke plus intravenous infusion of 100 ml normal saline alone daily for 7 days.

Category

Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Farshchian Hospital
Full name of responsible person
Sajedeh Nazari
Street address
Farshchian Hospital, Mirzadeh Eshghi Ave.
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences
Proportion provided by this source
100
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
Farshchian Hospital
Full name of responsible person
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Person responsible for updating data

Contact

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