Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of citicoline versus placebo on clinical signs in patients with acute ischemic and hemorrhagic stroke: a triple blind control trial

Protocol summary

Summary

Objectives: To assess the effect of citicoline versus placebo on clinical signs in patients with acute ischemic and hemorrhagic stroke Design: a triple blind randomized clinical trial. Setting and conduct: The eligible patients with acute ischemic and hemorrhagic stroke who will refer to Sina Hospital during the study period will be enrolled into the trial. Inclusion criteria: (a) age of 18 to 85 years; (b) acute stroke; (c) NIHSS score between 6 to 22. Exclusion criteria: (a) previous history of stroke; (b) renal or liver failure; (c) cancer; (d) active infectious disease during last month; (e) trauma or surgery during last month; (f) history of collagen vascular disease; (g) immunosuppressive medications or corticosteroid; (h) signs of brain hernia; (i) convulsion at the time of stroke; (j) neurologic disease or dementia; (k) pregnancy or breastfeeding; (l) receiving vasodilator medications. Intervention group: Infusion of citicoline 1 gr in normal saline (overall 20 ml) once daily for 10 days. Control group: Infusion of 20 ml normal saline once daily for 10 days Primary outcome: (a) measuring stroke score based on NIHSS at baseline and 10 and 90 days after intervention; (b) measuring stroke score based on Barthel Index at baseline and 10 and 90 days after intervention; (c) Measuring stroke score based on Modified Rankin Scale at baseline and 10 and 90 days after intervention. Secondary outcome: Nothing. Randomization: The patients will be randomly assigned to intervention and control groups using block randomization of 4 group. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Therefore, the trial will be run as triple blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201601289014N90**
Registration date: **2016-02-24, 1394/12/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-02-24, 1394/12/05

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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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

2016-02-20, 1394/12/01

Expected recruitment end date

2017-02-18, 1395/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of citicoline versus placebo on clinical signs in patients with acute ischemic and hemorrhagic stroke: a triple blind control trial

Public title
Effect of citicoline versus placebo on clinical signs in patients with acute ischemic and hemorrhagic stroke
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: (a) age of 18 to 85 years; (b) acute stroke; (c) NIHSS score between 6 to 22. Exclusion criteria: (a) previous history of stroke; (b) renal or liver failure; (c) cancer; (d) active infectious disease during last month; (e) trauma or surgery during last month; (f) history of collagen vascular disease; (g) immunosuppressive medications or corticosteroid; (h) signs of brain hernia; (i) convulsion at the time of stroke; (j) neurologic disease or dementia; (k) pregnancy or breastfeeding; (l) receiving vasodilator medications.
Age
From **18 years** old to **85 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **160**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Randomization: The patients will be randomly assigned to intervention and control groups using block randomization of 4 group. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Therefore, the trial will be run as triple blind.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Postal code
6517838695
Approval date
2016-01-23, 1394/11/03
Ethics committee reference number
IR.UMSHA.REC.1394.448

Health conditions studied

1

Description of health condition studied
stroke
ICD-10 code
I64
ICD-10 code description
Stroke, not specified as haemorrhage or infarction

Primary outcomes

1

Description
Measuring stroke score (NIHSS)
Timepoint
at baseline and 10 and 90 days after intervention
Method of measurement
based on NIHSS

2

Description
Measuring stroke score (Barthel Index)
Timepoint
at baseline and 10 and 90 days after intervention
Method of measurement
based on Barthel Index

3

Description
Measuring stroke score (Modified Rankin Scale)
Timepoint
at baseline and 10 and 90 days after intervention
Method of measurement
based on Modified Rankin Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Infusion of citicoline 1 gr in normal saline (overall 20 ml) once daily for 10 days

Category

Treatment - Drugs

2

Description

Control group: Infusion of 20 ml normal saline once daily for 10 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr Shahir Mazaheri

Street address

Sina 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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Hamadan

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

Sina Hospital

Full name of responsible person

Dr Shahir Mazaheri

Position

Neurologist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Department of Epidemiology

Full name of responsible person

Dr Jalal Poorolajal

Position

Associate Professor

Other areas of specialty/work

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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