

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Sep 2026

Effect of high-dose oral Acetyl-L-carnitine versus placebo on serum level of oxidative and nirtosative stress and clinical outcomes in patients with ischemic stroke: a double-blind randomized clinical trialApproved

Protocol summary

Study aim

To assess the effect of high-dose oral Acetyl- L-Carnitine versus placebo on serum level of oxidative and nirtosative stress and clinical outcomes in patients with ischemic stroke

Design

This a double-blind randomized clinical trial, phase II, in which 90 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

This study was conducted as a clinical, randomized, and double blind clinical trial on patients with ischemic stroke referred to Farshchian Sina Hospital in Hamedan. The researcher and participants were blinded.

Participants/Inclusion and exclusion criteria

Criteria for entering the study: aged 18 to 85 years; focal neurological disorder; Ischemic stroke; Non-pregnancy and lactation; Hospitalization within the first 24 hours after stroke; ischemic stroke for the first time. Exit criteria: Evidence on acute or chronic intracerebral hemorrhage and brain aneurysm; The existence of any other etiology other than ischemia.

Intervention groups

Intervention group: Routine stroke treatment plus oral Acetyl-L-carnitine capsule, 500 mg, every 8 hours, for 3 days. Control group: Routine stroke treatment plus oral placebo, every 8 hours, for 3 days.

Main outcome variables

Serum level of lipid peroxidation, nitric oxide, total antioxidant capacity, thiol, activity of glutathione peroxidase, catalase, superoxide dismutase, NIHSS, mRS

General information

Reason for update

changing the time point of National Institutes of Health Stroke Scale and Modified Rankin Scale for Neurologic

Disability outcomes

Acronym

IRCT registration information

IRCT registration number: **IRCT20150629022965N17**

Registration date: **2018-07-25, 1397/05/03**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-17, 1398/11/28**

Update count: **1**

Registration date

2018-07-25, 1397/05/03

Registrant information

Name

Maryam Mehrpooya

Name of organization / entity

School of Pharmacy, Hamadan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-21, 1397/04/30

Expected recruitment end date

2019-04-19, 1398/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of high-dose oral Acetyl-L-carnitine versus placebo on serum level of oxidative and nirtosative stress and clinical outcomes in patients with ischemic stroke: a double-blind randomized clinical trialApproved

Public title

Effect of high-dose oral Acetyl-L-carnitine versus placebo on serum level of oxidative and nirtosative stress and clinical outcomes in patients with ischemic stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18 to 85 years old Ischemic stroke Stroke for the first time Local neurologic disorder Patients who have been admitted for the first 24 hours after the stroke

Exclusion criteria:

Pregnancy or breastfeeding Inflammatory disease Asthma History of anaphylaxis shock

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double-blind

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamedan University of Medical Sciences

Street address

Pharmacy school, Hamadan University of Medical Sciences, in front of Mardom park, Shahid Fahmideh Blvd, Hamedan

City

Hamedan

Province

Hamadan

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6517838678

Approval date

2018-06-08, 1397/03/18

Ethics committee reference number

IR.UMSHA.1397.163

Health conditions studied

1

Description of health condition studied

ischemic stroke

ICD-10 code

I63

ICD-10 code description

Cerebral infarction

Primary outcomes

1

Description

Serum level of lipid peroxidation

Timepoint

Before intervention and 3 days after intervention

Method of measurement

kit

2

Description

Serum levels of nitric oxide

Timepoint

Before intervention and 3 days after

Method of measurement

kit

3

Description

Serum levels of total antioxidant capacity

Timepoint

Before intervention and 3 days after

Method of measurement

kit

4

Description

Catalase activity

Timepoint

Before intervention and 3 days after intervention

Method of measurement

kit

5

Description

Activity of superoxide dismutase

Timepoint

Before intervention and 3 days after intervention

Method of measurement

kit

6

Description

Serum level of thiol

Timepoint

Before intervention and 3 days after intervention

Method of measurement

kit

7

Description

Activity of Glutathione Peroxidase

Timepoint

Before intervention and 3 days after intervention

Method of measurement

kit

8

Description

National Institutes of Health Stroke Scale

Timepoint

Before intervention and 90 days after intervention

Method of measurement

Questionnaire

9

Description

Modified Rankin Scale for Neurologic Disability

Timepoint

Before intervention and 90 days after intervention

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, patients will receive oral Acetyl-L-Carnitine, one 500mg capsule, at the dose of 1 g three times a day (every 8 hours) for 3 days in addition to the standard treatment.

Category

Treatment - Drugs

2

Description

Control group: In the control group, patients will receive placebo at the dose of 1 g, three times a day (every 8 hours) for 3 days in addition to the standard treatment.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamedan Farshchian Sina Hospital

Full name of responsible person

Maryam Mehrpooya

Street address

Farshchian Sina Hospital, Mirzadeh Eshghi St.,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

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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

Hamedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding*empty***Country of origin****Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Maryam Mehrpooya

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

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student

Latest degree

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available