Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 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 ofoxidative 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 Disability outcomes

General information

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

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

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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

Postal code
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
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Sponsors / Funding sources

1

Sponsor
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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
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Maryam Mehrpooya
Position
Assistant Professor
Latest degree
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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