Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Effect of L-carnitine supplementation on clinical status, anthropometric indices, and serum levels of some oxidative stress and inflammation biomarkers in ischemic stroke patients.

Protocol summary

Study aim

Effect of L-carnitine supplementation on clinical status, anthropometric indices, and serum levels of some oxidative stress and inflammation biomarkers in ischemic stroke patients.

Design

The clinical trial has a control group, with parallel groups, three blinded, randomized, on 82 case and control patients. The random number table will be used for randomization.

Settings and conduct

This study is conducted at Golestan Hospital, Jundishapur University of Medical Sciences, Ahvaz. 24 to 48 after the onset of symptoms, patients will be assigned by filling out a written consent form. Before the intervention and on the seventh day of the intervention, anthropometric measurements, TMT index, mRs and NIHSS indices are measured and blood samples are taken to test the serum levels of CRP, TAC, MDA and PAB index. All patients, the executive staff of the intervention and the people analyzing the results are unaware of the type of vial used in each group.

Participants/Inclusion and exclusion criteria

Diagnosis of ischemic stroke Age above 18 years BMI >18.5 NIHSS score greater than 10 and less than 22 The onset of symptoms is less than 24 hours. No history of other neurological diseases Having a focal neurological disorder

Intervention groups

The intervention group will receive three vials of 1000 mg L-carnitine daily and the placebo group will receive three 1000 mg vials of distilled water daily for 7 days.

Main outcome variables

Reduction of oxidative stress inflammation markers Improvement of clinical condition and anthropometric indicators

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221206056734N1**
Registration date: **2023-02-11, 1401/11/22**
Registration timing: **registered_while_recruiting**

Last update: **2023-02-11, 1401/11/22**
Update count: **0**

Registration date

2023-02-11, 1401/11/22

Registrant information

Name

Samaneh Hajjarzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3553 9049

Email address

hajarzadeh70@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-07-23, 1402/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of L-carnitine supplementation on clinical status, anthropometric indices, and serum levels of some oxidative stress and inflammation biomarkers in ischemic stroke patients.

Public title
Effect of L-carnitine in Ischemic Stroke
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosing and confirming the occurrence of ischemic stroke through clinical and neurological examinations by a neurologist and brain imaging (CT-Scan or MRI) Be over 18 years old. Body mass index be more than 18.5. Having an NIHSS score of greater than 10 and less than 22. The onset of symptoms be less than 24 hours. Having focal neurologic deficit Insensitivity to L-carnitine supplement No history of previous stroke, craniotomy, and other CNS diseases such as seizures, epilepsy, brain tumor, severe brain injury, multiple sclerosis, Alzheimer's, Parkinson's, etc. Not taking antioxidant or anti-inflammatory supplements or multivitamins in the last three months Not suffering from chronic or acute liver and kidney disorders (kidney failure and dialysis)
Exclusion criteria:
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **82**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to randomly assign people to each of the studied groups, block randomization is used. For this study, 7 blocks of 10 and one block of 12 are considered, and an equal number of people from two intervention and control groups are entered in each block. The randomization unit for this study will be individual and for this purpose, a table of random numbers will be used.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Supplement and placebo are prepared by Pars Behrozan Jam pharmaceutical company and are labeled with two different letters. All patients, researchers, data analysts and outcome assessors are unaware of the contents of each label until the end of the study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Ahvaz JundiShapur University of Medical Sciences
Street address
Ahvaz, Golestan, North Esfand St., Ahvaz Jundishapur University of Medical Sciences, Faculty of Paramedicine
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Approval date
2022-12-03, 1401/09/12
Ethics committee reference number
IR.AJUMS.REC.1401.416

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
National Institutes of Health Stroke Scale (NIHSS) score
Timepoint
Before the intervention and on the seventh day of the intervention
Method of measurement
The scoring checklist is completed through clinical examinations by a specialist.

2

Description
Modified Rankin Scale (mRs) score
Timepoint
Before the intervention, on the seventh day of the

intervention and three months after the intervention.

Method of measurement

The scoring checklist is completed through clinical examinations by a specialist.

3

Description

Temporal muscle thickness (TMT)

Timepoint

Before the intervention and on the seventh day of the intervention.

Method of measurement

Using ultrasound images

4

Description

C-reactive protein (CRP)

Timepoint

Before the intervention and on the seventh day of the intervention.

Method of measurement

blood test

5

Description

Total Antioxidant Capacity (TAC)

Timepoint

Before the intervention and on the seventh day of the intervention.

Method of measurement

blood test

6

Description

Malondialdehyde (MDA)

Timepoint

Before the intervention and on the seventh day of the intervention.

Method of measurement

blood test

7

Description

Pro-oxidant Antioxidant Balance (PAB)

Timepoint

Before the intervention and on the seventh day of the intervention.

Method of measurement

blood test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 41 patients with a diagnosis of stroke in the first 24 hours of hospitalization entered the study and will receive 3 vials of L-carnitine 1000 mg per day, prepared by Pars Behrouzan Jam Company, along with meals for 7 days. Patients receiving tube feeding will receive L-carnitine supplementation mixed into the gavage solution. Patients and executive staff will be unaware of the type of vial provided to patients.

Category

Treatment - Drugs

2

Description

Control group: 41 patients with a diagnosis of stroke in the first 24 hours of hospitalization entered the study and will receive 3 vials of double distilled water of 1000 mg per day prepared by Pars Behrouzan Jam Company along with meals for 7 days. Patients receiving tube feeding will receive placebo mixed into the gavage solution. Patients and executive staff will be unaware of the type of vial provided to patients.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital,Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Samaneh Hajjarzadeh

Street address

Golestan, Esfand street

City

Ahvaz

Province

Khouzestan

Postal code

61357159

Phone

+98 61 3311 0000

Fax

Email

hajarzadeh70@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Majid Karandish

Street address

Farvardin Ave., Golestan Blvd, School of Allied Medical Sciences

City
Ahvaz

Province
Khouzestan

Postal code
1579461357

Phone
+98 61 3311 2538

Email
mkarandish@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Pars Behrouzan Jam Company

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Samaneh Hajjarzadeh

Position
Ph.D. candidate

Latest degree
Master

Other areas of specialty/work
Nutrition

Street address
Padad, 12th street, number 82

City
Ahvaz

Province
Khouzestan

Postal code
6183986642

Phone
+98 61 3553 9049

Email
hajarzadeh70@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Majid Karandish

Position
professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
Golestan, Esfand street, paramedical faculty of Ahvaz Jundishapur University of Medical Sciences

City
Ahvaz

Province
Khouzestan

Postal code
61357159

Phone
+98 61 3311 2557

Email
mkarandish@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Samaneh Hajjarzadeh

Position
Ph.D candidate

Latest degree
Master

Other areas of specialty/work
Nutrition

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padad, 12th street, number 82

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Province
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Postal code
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Email
hajarzadeh70@gmail.com

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
Not applicable

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

Clinical Study Report
Not applicable
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