

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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**

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##### **Province**

Khuzestan

##### **Postal code**

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##### **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

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**Province**

Khouzestan

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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

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Padad, 12th street, number 82

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## 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

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## Person responsible for updating data

**Contact**

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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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## 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