

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation the effect of L-carnitine on insulin resistance and prognosis of patients with ischemic stroke admitted to the Intensive Care Unit of Alzahra hospital: randomized, double blinded clinical trial

Protocol summary

Study aim

The aim of this study is the evaluation of the effect of L-carnitine on insulin resistance and prognosis in ischemic stroke patients admitted to the intensive care unit.

Design

A randomized, controlled, double-blind, parallel-group clinical trial of 40 patients. Eligible patients are allocated to the drug or placebo group by simple randomization.

Settings and conduct

Admitted patients to the intensive care unit (ICU) are inspected for whether they have inclusion or exclusion criteria. Then eligible ischemic stroke patients randomly allocated to the drug or placebo group. On the first and seventh day, after six to eight overnight fasting, a blood sample is drawn to determine the level of insulin, C-reactive protein (CRP), and L-carnitine. The degree of insulin resistance on these days is determined by the Homeostatic model assessment for insulin resistance (HOMA-IR) formula. lab data and information about the severity of illness are also collected.

Participants/Inclusion and exclusion criteria

The inclusion criteria of this study are patients 18 years or older with a diagnosis of ischemic stroke. Patients with a history of L-carnitine hypersensitivity, taking L-carnitine in the last month or require dialysis are excluded.

Intervention groups

500 mg L-carnitine and the placebo are administered every eight hours for six days to the drug and placebo group, respectively.

Main outcome variables

Main outcomes of this clinical trial include the determination and comparison of mean fasting blood insulin, sugar, and CRP level, HOMA-IR score, L-carnitine serum level, and Glasgow coma scale (GCS) score at the initial and the end of the intervention; mean duration of mechanical ventilation and length of stay in the ICU and

hospital; mean sequential organ function assessment (SOFA) and frequency of sepsis and mortality incidence between two groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200509047365N1**

Registration date: **2020-06-02, 1399/03/13**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-02, 1399/03/13**

Update count: **0**

Registration date

2020-06-02, 1399/03/13

Registrant information

Name

malihe nejati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 7071

Email address

nejati@pharm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2020-06-20, 1399/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of L-carnitine on insulin resistance and prognosis of patients with ischemic stroke admitted to the Intensive Care Unit of Alzahra hospital: randomized, double blinded clinical trial

Public title

Effect of L-carnitine on insulin resistance

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 18 years or older Diagnosis of ischemic stroke

Exclusion criteria:

A diagnosis of hemorrhagic stroke History of hypersensitivity to L-carnitine History of taking L-carnitine in the last month Required dialysis

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

By selecting labeled cards, "drug group" or "placebo group", Patients are randomly allocated to drug or placebo groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind study; participants, care providers, and investigators are unaware of prescribed drugs for the study groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1**

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical sciences

Street address

Department of clinical pharmacy and pharmaceutical practices, faculty of pharmacy, Isfahan University of Medical sciences, Hizar jarib street

City

Isfahan

Province

Isfahan

Postal code

7346181746

Approval date

2019-02-06, 1397/11/17

Ethics committee reference number

IR.MUI.MED.REC.1397.199

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**

Determination and comparison of mean insulin resistance before and after intervention

Timepoint

Before intervention and 7 days after intervention

Method of measurement

Homeostatic model assessment of insulin resistance (HOMA-IR)

2**Description**

Determination and comparison of Prognosis of two groups

Timepoint

Daily from day 1, before intervention to day 7 and 28 days after intervention

Method of measurement

Frequency of 28-day mortality and duration of mechanical ventilation, daily Glasgow Coma Scale and Sequential Organ Function Assessment scores, whether or not sepsis occurs through the intervention days based on SOFA score changes

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: L-carnitine 250 mg of Pursina Company, two tablets every 8 hours for six days orally or via nasogastric tube (NGT)

Category

Treatment - Drugs

2

Description

Control group: Placebo of Pursina Company two tablets every 8 hours for six days orally or via NGT

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Shadi Farsaei

Street address

Soffeh Blvd, Alzahra hospital

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Web page address

http://alzahra.mui.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh haghjou Javanmard

Street address

Vice chancellery research and technology, Bldg No. 4, Isfahan University of Medical Sciences and Health Services, Hizarjarib st.

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8174673461

Phone

+98 31 3668 8138

Email

research@mui.ac.ir

Web page address

https://research.mui.ac.ir/fa

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Malihe Nejati

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

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Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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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

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

Esfahan University of Medical Sciences

Full name of responsible person

Malihe Nejati

Position

Resident

Latest degree

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Other areas of specialty/work

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Street address

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