Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
Isfehan
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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8174675731
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alzahra@mui.ac.ir
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh haghjou Javanmard
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Vice chancellery research and technology, Bldg No. 4, Isfahan University of Medical Sciences and Health Services, Hizarjarib st.
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Phone
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Email
research@mui.ac.ir
Web page address
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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
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
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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