Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The Effect of L-Carnitine supplementation administration rout on inflammatory, metabolic markers and the prognosis of patients admitted to the intensive care unit

Protocol summary

Study aim
The effect of L-carnitine on inflammatory and metabolic markers and form of dministration (oral or injection) on the outcomes under study in Intensive Care Unit patients.

Design
The design of the study is a parallel type that will be done in three groups. One group is control and two groups are as interventions with different methods in administering L-carnitine. 45 patients were considered for each group and method of blinding is double-blind.

Settings and conduct
This study is to investigate the effect of L-carnitine supplementation and its administration method on changes in inflammatory and metabolic markers. The setting of this study is the Intensive Care Unit of Rasool Akram Hospital, Iran University of Medical Sciences. The effect of the type of interventions prescribed will be measured on the results of the study in the determined days after the intervention. The participants in the study and the doctors evaluating the outcomes of the study will be unaware of the type of interventions received by the patients.

Participants/Inclusion and exclusion criteria
The include criteria is to be at least 17 years old and hospitalized in the Intensive Care Unit, also the non-include criteria is a history of taking L-carnitine and having a heart disease.

Intervention groups
Patients will be randomly assigned to three groups. The control group will receive only placebo. The first intervention group will receive one gram of L-carnitine capsules every six hours for three to seven days, in addition to this, the second intervention group will receive three grams of L-carnitine intravenously every day for 12 hours for three to seven days. All study participants will receive all of their routine therapeutic interventions

Main outcome variables
inflammatory indicators; lipid profile; sofa score; Apache score; nutrition score, length of hospitalization; fasting blood sugar; Insulin resistance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170903036041N4**
Registration date: **2023-04-30, 1402/02/10**
Registration timing: **registered_while_recruiting**

Last update: **2023-04-30, 1402/02/10**
Update count: **0**

Registration date
2023-04-30, 1402/02/10

Registrant information

Name
Omid Moradi Moghadam

Name of organization / entity
Iran University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-21, 1402/02/01

Expected recruitment end date

2023-09-21, 1402/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of L-Carnitine supplementation administration rout on inflammatory, metabolic markers and the prognosis of patients admitted to the intensive care unit

Public title

The Effect of L-Carnitine supplementation administration rout on the prognosis of patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients admitted to the Intensive Care Unit At least 17 years old

Exclusion criteria:

History of taking L-carnitine supplements in the last month Taking corticosteroids and NSAIDs Severe cardiovascular diseases Pregnancy Breastfeeding

Age

From **17 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **135**

Randomization (investigator's opinion)

Randomized

Randomization description

After selecting the participants in the study using inclusion and non-inclusion criteria, to prevent the occurrence of bias in the selection of participants to intervention and control groups, we will use the randomization method to minimize the opinion of researchers in selecting participant to study groups. The block randomization method was used in this study. The size of the blocks is considered to be six and will be selected randomly so that it is not predictable to the participants based on the blocks. First, we will receive using Random Allocation software and by determining the sample size, the number of groups, the type of randomization and is random the order of the blocks in the software output and will be shown in the software output of groups with letters A, B and C. Then, after selecting each patient based on the inclusion and non-inclusion criteria, the project manager will be informed and he will tell the type of intervention of that patient based on the order of inclusion of patients and compliance with the number mentioned in the randomization output.

Blinding (investigator's opinion)

Double blinded

Blinding description

We will inform the supervisor after selecting each patient for the study and they are based on the randomized output of the randomization software and its matching to the patient's number the interventions will be sent in a form that is not known to the patients, prescriptive, and evaluator of the outcomes. For this, the shape and color of the interventions will be the same. Blinding process in this study is double blinded. Participants in the study will be blinded of interventions also the physicians will be blinded of the type of interventions received by the participants when they evaluated the outcome.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran university of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway

City

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Province

Tehran

Postal code

1449614535

Approval date

2023-02-22, 1401/12/03

Ethics committee reference number

IR.IUMS.REC.1401.958

Health conditions studied

1

Description of health condition studied

Patients admitted to the intensive care unit

ICD-10 code

Z09.9

ICD-10 code description

Follow-up examination after unspecified treatment for other conditions

Primary outcomes

1

Description

C-Reactive Protein

Timepoint

The beginning of the study, the third and seventh days after the intervention

Method of measurement

Blood test

2

Description

Erythrocyte Sedimentation Rate

Timepoint

The beginning of the study, the third and seventh days after the intervention

Method of measurement

Blood test

3

Description

Fasting Blood Sugar

Timepoint

The beginning of the study, the third and seventh days after the intervention

Method of measurement

Blood test

4

Description

Insulin

Timepoint

The beginning of the study, the third and seventh days after the intervention

Method of measurement

Blood test

Secondary outcomes

1

Description

Cholesterol

Timepoint

The beginning of the study, the third and seventh days after the intervention

Method of measurement

Blood test

2

Description

Triglyceride

Timepoint

The beginning of the study, the third and seventh days after the intervention

Method of measurement

Blood test

3

Description

Low-density lipoprotein

Timepoint

The beginning of the study, the third and seventh days after the intervention

Method of measurement

Blood test

4

Description

High-density lipoprotein

Timepoint

The beginning of the study, the third and seventh days after the intervention

Method of measurement

Blood test

5

Description

SOFA score

Timepoint

The beginning and end of the study

Method of measurement

SOFA checklist

6

Description

APACHE II score

Timepoint

The beginning and end of the study

Method of measurement

APACHE II score

7

Description

Nutrition score

Timepoint

The beginning and end of the study

Method of measurement

NUTRIC score

8

Description

length of stay

Timepoint

Hospitalization days

Method of measurement

Count the number of days

Intervention groups

1

Description

Intervention group: L-carnitine capsules will be prescribed 1 gram orally, 4 times a day for 3-7 days.

Category

Treatment - Other

2

Description
Intervention group: L-carnitine will be administered intravenously over 12 hours a day, for 3-7 days.
Category
Treatment - Other

3

Description
Control group: Patients in this group will receive only the usual medical services and will not receive a placebo.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul Akram hospital
Full name of responsible person
Omid Moradimoghadam
Street address
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Sponsors / Funding sources

1

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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
Iran 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
Iran University of Medical Sciences
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Person responsible for updating data

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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
No - There is not 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
Yes - There is 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

Title and more details about the data/document
Finding of the study, demographic data of participants in the study, in addition to descriptive and analytical analysis of variables.

When the data will become available and for how long
Availability six months after the end of study.

To whom data/document is available
Critical care fellowships, anesthesiologists, internists.

Under which criteria data/document could be used
Anyone who has a request for information about the results of this research.

From where data/document is obtainable
Iran University of Medical Sciences.

What processes are involved for a request to access data/document
By referring to the central library and clinical trial center in Iran University of Medical Sciences can access to the documents of participants, data and results.

Comments