

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### The Effect of L-Carnitine supplementation administration route 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 administration (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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6653 9233

##### Email address

moradimoghadam.o@iums.ac.ir

##### 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**

Tehran

**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

Rasoul Akram hospital, Niyayesh St, Sattarkhan St

##### City

Tehran

##### Province

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##### Postal code

1445613131

##### Phone

+98 21 6653 9260

##### Email

moradimoghadam.o@iums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Hossein Keyvani

##### Street address

Iran University of Medical Sciences, Shahid Hemmat Highway

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##### Province

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1449614535

##### Phone

+98 21 8670 2503

##### Email

research@iums.ac.ir

##### 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

##### Full name of responsible person

Arzhang Ebrahimi Fard

##### Position

Fellowship

##### Latest degree

Specialist

##### Other areas of specialty/work

Anesthesiology

##### Street address

Rasoul Akram hospital, Niyayesh St, Sattarkhan St

##### City

Tehran

##### Province

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##### Postal code

1445613131

##### Phone

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##### Email

emohaghegh96@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Omid Moradimoghadam

##### Position

Associate professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Anesthesiology

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##### City

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##### Province

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moradimoghadam.o@iums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Arzhang Ebrahimi Fard  
**Position**  
Fellowship  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
Rasoul Akram hospital, Niyayesh St, Sattarkhan St  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1445613131  
**Phone**  
+98 21 6653 9260  
**Email**  
emohaghegh96@yahoo.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

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