Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

The potential effect of parenteral L-carnitine on hospitalized patients with moderate to severe COVID-19

Protocol summary

Study aim
The potential effect of parenteral L-carnitine in hospitalized patients with moderate to severe COVID-19
Design
This double blind clinical trial has two intervention and control groups, which are a total of 100 patients and are randomly divided into two groups. The groups are parallel.
Settings and conduct
Hospitalized patients with COVID-19 will be divided into 2 groups by permuted block randomization with envelopes. The study is double-blind in which the data collector and participants will be blind. Patients will be given parenteral L-carnitine or its similar placebo at a dose of 100mcg/Kg until hospitalization or up to 14 days.
Participants/Inclusion and exclusion criteria
- Adults aged 18 years or older - Positive PCR test for COVID-19 or evidence against the disease - Patients with moderate to severe disease - Signs and symptoms compatible with COVID-19 disease according to the Iranian Ministry of Health protocol - Prior to the fifth day of symptoms onset
Intervention groups
Administering 100 mcL/kg (20 mg/Kg) of parenteral L-Carnitine in addition to the standard care therapy Until the time of hospitalization or up to 14 days
Main outcome variables
Disease severity Length of hospitalization mortality Time to improve clinical symptoms

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20170609034406N10**
Registration date: **2023-01-17, 1401/10/27**
Registration timing: **prospective**
Last update: **2023-01-17, 1401/10/27**
Update count: **0**
Registration date
2023-01-17, 1401/10/27

Registrant information
Name
Afshin Gharekhani
Name of organization / entity
Faculty of Pharmacy/Tabriz University of Medical Sciences
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-02-20, 1401/12/01
Expected recruitment end date
2024-02-20, 1402/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The potential effect of parenteral L-carnitine on hospitalized patients with moderate to severe COVID-19

Public title
The effect of parenteral L- carnitine on patients with COVID-19
Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

adults aged 18 years or older Positive PCR test for COVID-19 Patients with moderate to severe disease Signs and Symptoms compatible with COVID-19 disease according to the Iranian Ministry of Health protocol Prior to the fifth day of symptoms onset

Exclusion criteria:

Pregnancy Lactation HIV Infection History of taking L-carnitine supplement in the recent Month known immunosuppression condition or any active malignancy Patients with hypothyroidism or hyperthyroidism patients with regular aerobic training (more than 3 times a week with further than 2 hours each time) History of allergy to L-carnitine or its analogues History of or an increased risk for seizure

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **100**

More than 1 sample in each individual

Number of samples in each individual: **2**

serum

Randomization (investigator's opinion)

Randomized

Randomization description

This study will use the permuted block randomization method to assign patients into control and treatment groups. This study will have 25 blocks containing 4 patients allocated to treatment and the control group. Random numbers in this study will be generated using excel software to determine coalitions, and study groups randomly.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study will be conducted in a double-blind manner, none of the prescribers and patients and data collectors will know which of the patients received L-carnitine or placebo, and only through the numbers provided by The system was given to patients, it will be diagnosed.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Research Vice-Chancellor, Third floor, No. 2, Central Building, Tabriz University of Medical Sciences, Golgasht Street, Tabriz

City

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Province

East Azarbaijan

Postal code

5766414766

Approval date

2022-11-19, 1401/08/28

Ethics committee reference number

IR.TBZMED.REC.1401.749

Health conditions studied

1

Description of health condition studied

COVID _19

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes

1

Description

The length of hospitalization

Timepoint

At the end of study

Method of measurement

Comparing the number of hospitalization days between the intervention group and control group

2

Description

Disease severity

Timepoint

Daily

Method of measurement

Disease Severity Checklist in NIH Guidelines

3

Description

Mortality

Timepoint

End of study

Method of measurement

Patient file

4

Description
Time to improve clinical symptoms
Timepoint
Daily
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Serum Ferritin level
Timepoint
At the beginning and end of the study
Method of measurement
Ferritin kit

2

Description
Serum LDH (Lactate Dehydrogenase) level
Timepoint
At the beginning and end of the study
Method of measurement
Alkaline phosphatase Assay Kit (DGKC Kit)

3

Description
Serum D_dimer level
Timepoint
At the beginning and end of the study
Method of measurement
D_dimer ELISA kit

4

Description
serum C_ reactive protein (CRP) level
Timepoint
At the beginning and end of the study
Method of measurement
CRP ELISA Kit

5

Description
Oxygen saturation
Timepoint
Daily
Method of measurement
oxymeter

6

Description
Require for mechanical ventilation
Timepoint
daily
Method of measurement
observation

7

Description
L-carnitine serum level
Timepoint
baseline and end of the study
Method of measurement
ELISA kit

Intervention groups

1

Description
Intervention group (L-carnitine + standard care): 50 patients with COVID-19 diagnosis will be included in the study according to the inclusion and exclusion criteria, and will receive 100mcL/kg (20 mg/kg) parenteral L-carnitine once daily until hospitalization or up to 14 days along with the standard care recommended by the Iranian Ministry of Health protocol.
Category
Treatment - Drugs

2

Description
Control group: (placebo + standard care): 50 patients with COVID-19 will be included in the study based on the inclusion and exclusion criteria, and will receive the equivalent volume of L-carnitine as100mcL/kg from normal saline serum once daily until hospitalization or a maximum of 14 days along with the standard care recommended by the Iranian Ministry of Health protocol
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Haspital
Full name of responsible person
Afshin Gharekhani
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2

Recruitment center

Name of recruitment center
Emam Reza Hospital

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Afshin Gharekhani

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)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information.
Study Protocol
Yes - There is 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
Title and more details about the data/document
Results and data on primary and secondary outcomes will be shared.
When the data will become available and for how long
3 years after publication
To whom data/document is available
The results and data will be available to researchers working in academic and scientific institutions.
Under which criteria data/document could be used
For meta-analysis only
From where data/document is obtainable
by email
What processes are involved for a request to access data/document
by email only
Comments