

# 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 mL/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)

###### Phone

+98 41 3334 1315

###### Email address

gharekhania@tbzmed.ac.ir

##### 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**

Tabriz

#### **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 as 100mcL/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 Hospital

#### **Full name of responsible person**

Afshin Gharekhani

#### **Street address**

Sina Educational and Medical Center, between Shahid Montazeri and Hafez intersections, Azadi Street

#### **City**

Tabriz

#### **Province**

East Azarbaijan

#### **Postal code**

5147663419

#### **Phone**

+98 41 3549 8342

#### **Email**

anqarekhani@yahoo.com

## 2

### Recruitment center

**Name of recruitment center**

Emam Reza Hospital

**Full name of responsible person**

Afshin Gharekhani

**Street address**

Golgasht street

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5147663419

**Phone**

+98 41 3337 3901

**Email**

gharekhanian@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr Afshin Gharekhani

**Street address**

No 2 central building, Tabriz University of Medical sciences, Golgasht Street, Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5766414766

**Phone**

+98 41 3337 2250

**Email**

gharekhanian@tbzmed.ac.ir

**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

**Street address**

No. 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street, Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614766

**Phone**

+98 41 3337 2250

**Email**

gharekhanian@tbzmed.ac.ir

## Person responsible for scientific 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

**Street address**

Faculty of Pharmacy, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz, Iran

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5147663419

**Phone**

+98 41 3230 5351

**Email**

gharekhanian@tbzmed.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Farnaz Naeimzadeh

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Faculty of Pharmacy , Tabriz University of Medical Science , Daneshgah Street , Tabriz , Iran

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5147663419

**Phone**

+98 41 3333 7244

**Email**

f.naeimzadeh372@gmail.com

**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**