

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of L-Carnitine on patients with moderate to severe condition of Covid-19 admitted to critical care unit

Protocol summary

Study aim

Evaluation of the effect of L-Carnitine on patients with moderate to severe condition of Covid-19 admitted to critical care unit

Design

The study will be double blind and clinical trial. 64 patients will be randomly divide into 2 groups. The groups are parallel. The trial phase is 3.

Settings and conduct

Patients with Covid-19 with moderate disease severity (with Apache score above 25) severely hospitalized in intensive care units of Amir Al-Momenin Hospital in Arak are divided into 2 groups by simple randomization with envelopes. The study is double-blind in which outcome evaluator and data analyst and participant are kept blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Suffering Covid-19 without intubation, apache less than 25, 28 to 75 years, absence of acute asthma, absence of acute pulmonary hemorrhage, absence of lung tumor, absence of untreated pneumothorax, do not take anticoagulants (coumadin group such as warfarin), no history of kidney or liver disease, no diabetes (because of the risk of hypoglycemia), no history of seizures
Exclusion criteria: Death, patient dissatisfaction with attending the study for any reason

Intervention groups

Intervention group: In addition to routine treatment, patients will receive 1 gram of L-carnitine supplement per day (Karen 1000 mg L-carnitine tablets) for 7 days.
Control group: Routine treatment of patients receiving Covid-19 based on protocol with placebo.

Main outcome variables

Intravenous blood gas samples, disease severity, length of hospital stay, mortality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N165**

Registration date: **2021-09-10, 1400/06/19**

Registration timing: **prospective**

Last update: **2021-09-10, 1400/06/19**

Update count: **0**

Registration date

2021-09-10, 1400/06/19

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

Email address

f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-09-23, 1401/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of L-Carnitine on patients with moderate to severe condition of Covid-19 admitted to critical care unit

Public title

Evaluation of the effect of L-Carnitine on patients with moderate to severe condition of Covid-19 admitted to critical care unit

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Suffering Covid-19 without intubation Apache less than 25 28 to 75 years Absence of acute asthma Absence of acute pulmonary hemorrhage Absence of lung tumor Absence of untreated pneumothorax Do not take anticoagulants (coumadin group such as warfarin) No history of kidney or liver disease No diabetes (because of the risk of hypoglycemia) No history of seizures

Exclusion criteria:

Death Patient dissatisfaction with attending the study for any reason

Age

From **28 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization with random allocation with envelopes in 3 groups A and B and C. In this method, we selected a number of cards or letters as an intervention group and the same number of cards for the control group, then the cards were merged. One card was taken out and its allocation was registered and the card was returned to the other cards after leaving. Then the cards are merged again and we remove another card. This process continues to reach a random sequence according to sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

In terms of patient blindness, the complementary intern does not know the groupings, and general anesthesia and drug injections are performed by an anesthesiologist. Outcome assessor and data analyzer and participant are blind (double blind). Outcome assessor and data analyzer and participant don't aware from grouping. The intern is unaware of the drugs prescribed in each group and the anesthesiologist prepares the drugs and provides them to the intern. Also,

the patients do not know about their group.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Arak University of Medical Sciences

Street address

Ethics committee, Research center, Payambar Azam complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2021-08-08, 1400/05/17

Ethics committee reference number

IR.ARAKMU.REC.1400.124

Health conditions studied**1****Description of health condition studied**

With Covid-19 with moderate disease severity

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes**1****Description**

Intravenous blood gas samples

Timepoint

Daily

Method of measurement

Intravenous blood samples

2**Description**

Disease severity

Timepoint

Daily

Method of measurement

Checklist Apache II

3

Description

length of hospital stay

Timepoint

End of study

Method of measurement

Patient file

4

Description

Mortality

Timepoint

End of study

Method of measurement

Patient file

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to routine treatment, patients will receive 1 gram of L-carnitine supplement per day (Karen 1000 mg L-carnitine tablets) for 7 days.

Category

Treatment - Drugs

2

Description

Control group: Routine treatment of patients receiving Covid-19 based on protocol with placebo.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin hospital

Full name of responsible person

Dr Behnam Mahmodie

Street address

Amiralmomenin Hospital, Basij square, Sardasht

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Email

mahmodie@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Alireza Kamali

Street address

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

Email

alikalaliir@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr Hesamedin Modir

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Valiasr Hospital, Valiasr square, Shahid Shirodi street

City

Arak

Province

Markazi

Postal code
3814957558
Phone
+98 86 3222 2003
Email
modir.he@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Behnam Mahmodie
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Valiasr Hospital, Valiasr squire, Shahid Shirodi street
City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 3222 2003
Email
mahmodie@arakmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr seyed Yousef Shahtaheri
Position

Anesthesiologist
Latest degree
Specialist
Other areas of specialty/work
Street address
Medicine department, Payambar Azam complex, Basij square, Sardasht, Arak, Iran
City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 3222 2003
Fax
+98 86 3222 2003
Email
fa.farokhi@gmail.com
Web page address

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