

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effects of L-carnitine supplementation on inflammatory factors, oxidative stress and clinical outcomes in sepsis patients admitted to the intensive care unit (ICU): A double-blind randomized clinical controlled trial

Protocol summary

Study aim

Determining the effect of L-carnitine supplementation on inflammatory factors, oxidative stress and clinical outcomes in patients with sepsis admitted to the intensive care unit (ICU)

Design

A double-blind, randomized controlled clinical trial with parallel groups on 60 patients. Randomization using a valid website and 4-blocking method.

Settings and conduct

This clinical trial will be performed on patients admitted to the ICU of Al-Zahra Hospital. L-Carnitine and placebo are given to the patient in exactly the same packaging. Patients and researchers will not be aware of the type of intervention.

Participants/Inclusion and exclusion criteria

Patients aged ≥ 18 years with sepsis admitted to the Intensive Care Unit (ICU) of Al-Zahra Hospital

Intervention groups

Three doses of 1000 mg L-carnitine per day in the intervention group Three doses of placebo 1000 mg daily in the control group

Main outcome variables

Before and after the study, inflammatory status including ESR and CRP, CBC, oxidative stress indices including TOS and TAC, The Acute Physiology and Chronic Health Evaluation (APACHE II), sequential organ failure assessment (SOFA), quick-SOFA (qSOFA)) And the patient's nutritional status form in ICU (NUTRIC score), serum albumin, BUN and creatinine, liver function tests (ALT and AST) and LDH will be evaluated.

General information

Reason for update

Changes in some outcomes and the date of the

participants' recruitment due to the conditions of the Covid-19 pandemic

Acronym

IRCT registration information

IRCT registration number: **IRCT20201129049534N1**

Registration date: **2021-05-02, 1400/02/12**

Registration timing: **prospective**

Last update: **2023-01-19, 1401/10/29**

Update count: **1**

Registration date

2021-05-02, 1400/02/12

Registrant information

Name

Mohammad bagherniya

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-27, 1400/03/06

Expected recruitment end date

2022-05-27, 1401/03/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of L-carnitine supplementation on inflammatory factors, oxidative stress and clinical outcomes in sepsis patients admitted to the intensive care unit (ICU): A double-blind randomized clinical controlled trial

Public title

"The effects of L-carnitine supplementation on septic patients"

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of sepsis based on blood culture and approval of an ICU specialist and anesthesiologist and infectious disease specialist Gastrointestinal with normal function and intestinal nutrition criteria Accept informed consent Age ≥ 18

Exclusion criteria:

Patient or family dissatisfaction Patients who are hospitalized in the ICU for less than 48 hours or do not have the possibility of intestinal feeding and patients who receive nutritional support with full intravenous feeding Patients who do not have an indication for intestinal nutrition on the first day and are confirmed and predicted based on the diagnosis of the intensive care unit that they will not be able to receive intestinal nutrition in the future. (Nausea, persistent vomiting, ileus, intestinal obstruction, uncontrolled diarrhea (> 500 ml per day), high-output fistula (> 500 ml per day), intestinal inaccessibility, incomplete resuscitation and hemodynamic instability Cancer patients undergoing chemotherapy and taking cisplatin Patients taking anticonvulsants (phenobarbital and phenytoin) Patients taking pivalic acid, valproic acid and Ifosfamide Patients taking levetiracetam Patients undergoing dialysis Patients with hyperthyroidism and hypothyroidism Pregnancy Severe and progressive septic shock Patients who are expected to die within 2 days of admission to the ICU Patients with BMI < 18.5 kg/m² admitted to the ICU

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done individually. Recruiting of each patient to the intervention or control groups is done

randomly with the help of 4 blocking method. This is done using a valid website to generate random numbers. (Each patient enters the control group or the intervention group is done by using random numbers)

<https://www.sealedenvelope.com/simple-randomiser/v1/lits>

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients in the intervention group will receive daily commercial L-carnitine supplements. Patients in the control group also receive a placebo, both of which are packaged and coated (blinded) in the same color, shape and smell, and differ only in the mark marked on it (A or B).

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee Vice-Chancellor in Research Affairs - Medical University of Isfahan

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Hezar-jerib Avenue, Isfahan University of Medical Sciences, School of Nutrition and Food Sciences

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8174673461

Approval date

2021-03-03, 1399/12/13

Ethics committee reference number

IR.MUI.RESEARCH.REC.1400.037

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

Sepsis

ICD-10 code

A41

ICD-10 code description

Other sepsis

Primary outcomes

1

Description

C reactive Protein (CRP)

Timepoint

At baseline and end of the study

Method of measurement

ELISA test

2

Description

Erythrocyte sedimentation rate (ESR)

Timepoint

At baseline and end of the study

Method of measurement

ELISA test

3

Description

Total antioxidant capacity (TAC)

Timepoint

At baseline and end of the study

Method of measurement

Commercial diagnostic kit

4

Description

Superoxide dismutase (SOD)

Timepoint

At baseline and end of the study

Method of measurement

Commercial diagnostic kit

Secondary outcomes

1

Description

28 mortality rate

Timepoint

End of the study

Method of measurement

Mathematically dividing the number of dead people by the total number of people using hospital records or telephone follow-up

2

Description

Complete blood count (CBC)

Timepoint

End of the study

Method of measurement

ELISA kits

Intervention groups

1

Description

Intervention group: 3000 mg of L-carnitine in 3 doses (1000 mg) 3 times a day for 7 days. From KAREN Trading Company

Category

Treatment - Drugs

2

Description

Control group: 3000 mg Maltodextrin in 3 doses (1000 mg) 3 times a day for 7 days. From KAREN Trading Company

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Mahdi Keshani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

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?

Yes
Title of funding source
Esfahan 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Information about the study will be published after the individuals are not identified and the project is completed.
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
Only for researchers working in academic and scientific institutions
Under which criteria data/document could be used
For further analysis
From where data/document is obtainable

Dr. Mohammad Bagherniya email:
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What processes are involved for a request to access data/document

After reviewing the request and making it fully clear about the purposes of using the data, the data will be provided.

Comments