Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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/lists

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

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

City
Isfahan

Province
Isfehan

Postal code
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 f the study
Method of measurement
Commercial diagnostic kit

4

Description
Superoxide dismutase (SOD)
Timepoint
At baseline and end f 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
Behruz Ataei
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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

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Mohammad Bagherniya

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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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: bagherniya@nutr.mui.ac.ir

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