Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Nov 2026

Evaluation of high-dose anti-inflammatory effects of l-carnitine in patients with critical ill in the intensive care unit

Protocol summary

Study aim
Determination of the effect of mega does l-carnitine supplementation on the level of inflammatory factors in critically ill patients in ICU

Design
This randomized and double-blind clinical trial with parallel and control groups will be conducted on 50 patients who will be randomly selected using the random number table.

Settings and conduct
Critically ill patients admitted to the intensive care unit to Imam Reza Hospital, Mashhad, Iran are chosen as the participants of the study. In this double-blind study, sealed opaque envelopes will be used to conceal the sequencing. Intervention group will receive the L-carnitine and control will receive placebo. The participants and person responsible for data collection are blind to group allocation and the type of treatment.

Participants/Inclusion and exclusion criteria
inclusion criteria:• Age of 18 years older, Conscious informed consent exteria criteria:Dissatisfaction with the patient or family of the patient to continue the intervention, Patients with liver and kidney failure, Patients who have cancer and are taking chemotherapy and cisplatin, Patients taking phenobarbital and phenytoin anti-inflammatory drugs,Patients taking pivolic acid, valproic acid, and fosfamide drugs,Patients undergoing dialysis.

Intervention groups
The intervention group will receive 3000 mg L-carnitine liquid supplements (Darou Pakhsh, Tehran, Iran), orally for 7 days. The control group will receive placebo (pasteurized drinking water) orally for 7 days.

Main outcome variables
Inflammation factors

General information

Reason for update
Title change

Acronym

IRCT registration information
IRCT registration number: **IRCT20151108024938N2**
Registration date: **2018-05-30, 1397/03/09**
Registration timing: **prospective**

Last update: **2024-01-11, 1402/10/21**
Update count: **1**

Registration date
2018-05-30, 1397/03/09

Registrant information

Name
Alireza Sedaghat

Name of organization / entity
Mashhad university of medical science

Country
Iran (Islamic Republic of)

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+98 51 3802 3701

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-06-09, 1397/03/19

Expected recruitment end date
2019-06-09, 1398/03/19

Actual recruitment start date
2018-07-01, 1397/04/10

Actual recruitment end date
2019-09-21, 1398/06/30

Trial completion date
2019-10-02, 1398/07/10

Scientific title
Evaluation of high-dose anti-inflammatory effects of l-

carnitine in patients with critical ill in the intensive care unit

Public title
Evaluation of high-dose anti-inflammatory effects of l-carnitine
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
Age of 18 years older Conscious informed consent Critical ill patients Patients with recently diagnosed critical ill
Exclusion criteria:
Dissatisfaction with the patient or family of the patient to continue the intervention Patients with liver and kidney failure Patients who have cancer and are taking chemotherapy and cisplatin Patients taking phenobarbital and phenytoin anti-inflammatory drugs Patients taking pivolic acid, valproic acid, and fosfamide drugs Patients undergoing dialysis
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **50**
More than 1 sample in each individual
Number of samples in each individual: **2**
at first and at the end of study has been take the blood (10 cc)
Actual sample size reached: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
25 patients with ARDS are simple randomly assigned to case and control groups. The entry of each patient into the case or control group will be randomized with the help of numbers in sealed envelopes.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, patients will be administered commercial L-carnitine liquid supplements at a dose of 3000 mg. Pasteurized drinking water will be used as a placebo. These will be randomly packaged and concealed (blinded) by a nurse. The medical team and the nutrition team will monitor the administration every day at specific hours. The patients will be given these supplements via gavage for a period of 7 days.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of medical university of mashhad
Street address
Imam Reza Hospital, Imam Reza Square
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Approval date
2018-04-09, 1397/01/20
Ethics committee reference number
IR.MUMS.fm.REC.1396.671

Health conditions studied

1

Description of health condition studied
Critical ill in intensive care units
ICD-10 code
R69
ICD-10 code description
Illness, unspecified

Primary outcomes

1

Description
IL-6
Timepoint
The first of study,the end of study 21th day
Method of measurement
ELISA

Secondary outcomes

1

Description
Anthropometric indices
Timepoint
Before and after study
Method of measurement
ELISA

2

Description
Mid-arm circumference (MAC)
Timepoint
Before and after study
Method of measurement
. The height of each patient is measured in the lying state or through the length of the ulna and the circumference of the middle of the non-dominant hand arm with a non-transient strip meter with an accuracy of 5.5 cm.

3

Description
Severity of illness
Timepoint
Before and after study
Method of measurement
Based on APACHEII questionnaire

4

Description
Examining organ dysfunction
Timepoint
Before and after study
Method of measurement
Based on sequential organ failure assessment (SOFA) questionnaire

5

Description
NUTRIC score questionnaire
Timepoint
Before and after study
Method of measurement
Based on Nutrition Risk in Critically ill (NUTRIC) questionnaire

6

Description
Acute Phosphorus Reactive Protein Level (CRP) Level - Inflammatory Cytokines Levels Including IL-10, IL-8 , IL-6, IL-4, IL-2, IL-1 β, IFN-γ, TNF-α
Timepoint
Before and after study
Method of measurement
ELISA

7

Description
Procalcitonin Factor
Timepoint
before and after study
Method of measurement
ELISA

Intervention groups

1

Description
intervention groups:25 patients with critical ill who receive commercially available l-carnitine supplements with a dose of 3000 Mg are given to the patients by nurses and supervised by the team during the specified period of time for 21 days in the treatment of Gavage.
Category
Treatment - Drugs

2

Description
Control group: 25 patients with Critical ill who receive pasteurized drinking water as a randomly packaged placebo are given to the patients by nurses and supervised by the team during the specified period of time for 21 days in the treatment of Gavage,the placebo is made that medical University of mashhad.Intervention groups and control groups are randomly assigned to case and control groups.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Alireza Sedaghat
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodii
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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
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Abdolreza Norozi

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Nutrition

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Person responsible for scientific inquiries

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Person responsible for updating data

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Farveh Yahyapour

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MSC Student

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Evaluation of high-dose anti-inflammatory effects of lcarnitine in critical ill patients in the intensive care unit

When the data will become available and for how long

This may be provided as an absolute date 1398,starting 6 months after publication

To whom data/document is available

The research data is exclusively accessible to the researchers working at universities and centers for scientific research

Under which criteria data/document could be used

Use of the data is only possible after publication of the article.

From where data/document is obtainable

Mashhad medical university, yahyapourof951@mums.ac.ir ,farvehyahyapour,

What processes are involved for a request to access data/document

6 Months

Comments