

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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 doses 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
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.

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

Email address

sedaghatar@mums.ac.ir

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 pivalic 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

Street address

Vice Chancellor for Research, Mashhad University of

Medical Sciences, Ghoreishi building, Daneshgah Street

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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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inquiries

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Full name of responsible person

Abdolreza Norozi

Position

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Latest degree

Subspecialist

Other areas of specialty/work

Nutrition

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Farveh Yahyapour

Position

MSC Student

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Master

Other areas of specialty/work

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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 l-carnitine 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