Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effect of L-Carnitine Supplementation on Some Inflammatory Biomarkers in Critically Ill Children in the Pediatric Intensive Care Unit (PICU): A Triple-Blind, Randomized Controlled Clinical Trial

Protocol summary

Study aim

Effect of L-carnitine supplementation on mean serum MDA, TAC and SOD concentration in critically ill children in the PICU. Effect of L-carnitine supplementation on mean serum CRP, ESR and IL_6 concentrations in critically ill children in the PICU. Effect of L-carnitine supplementation on mean NLR, MLR, and PLR in critically ill children in the PICU.

Design

A phase 3, randomized, parallel-group, triple-blind, controlled clinical trial on 36 patients. Randomization will be performed using a random number table.

Settings and conduct

This study will be conducted for one week on 38 critically ill children admitted to the PICU of the Zahra Mardani Azari Pediatric Research and Educational Center in Tabriz. Before the intervention, the Prism questionnaire will be completed for the children. Blood samples will be collected before and after the intervention to assess serum MDA, CRP, TAC, ESR, MLR, and NLR levels. All patients, the intervention staff, and the investigator analyzing the results will remain blinded to the intervention type in each group.

Participants/Inclusion and exclusion criteria

With parental consent, critically ill children (1 month to 12 years old) expected to stay in the PICU for more than 7 days will be included in the study. Patients with liver or kidney diseases, those undergoing hemodialysis or chemotherapy, and NPO patients will be excluded from the study.

Intervention groups

The intervention group will receive 50-100 mg/kg body weight of liquid L-carnitine daily (50 mg/kg body weight for infants under six months and 100 mg/kg body weight for older children, up to a maximum of 2 grams), while the placebo group will receive the same dose of distilled water daily for 7 days.

Main outcome variables

Reduction of oxidative stress, inflammation, and improvement of clinical status.

General information

Reason for update

The minimum length of ICU stay was revised from 3 days to 7 days to ensure that participants receive the full planned intervention duration (7 days). Since the intervention is administered daily for 7 consecutive days, inclusion of patients with shorter ICU stays could lead to incomplete exposure to the intervention and introduce bias in outcome assessment. Therefore, this modification was made to maintain methodological consistency and internal validity of the trial. The sample size was adjusted by increasing the anticipated attrition rate to account for potential dropouts and incomplete data, in order to improve the precision and reliability of the study results. This led to a slight increase (from 36 to 38) in the final recruitment target.

Acronym

IRCT registration information

IRCT registration number: **IRCT20221206056734N2**
Registration date: **2025-03-07, 1403/12/17**
Registration timing: **registered_while_recruiting**

Last update: **2026-06-20, 1405/03/30**
Update count: **1**

Registration date

2025-03-07, 1403/12/17

Registrant information

Name

Samaneh Hajjarzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3553 9049

Email address

hajarzadeh70@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-02-03, 1403/11/15

Expected recruitment end date

2026-02-04, 1404/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of L-Carnitine Supplementation on Some Inflammatory Biomarkers in Critically Ill Children in the Pediatric Intensive Care Unit (PICU): A Triple-Blind, Randomized Controlled Clinical Trial

Public title

The effect of L-carnitine in critically ill children admitted to PICU

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The age range of one month to 12 years. Critically Ill children expected to stay in the PICU for more than 7 days Legal guardian's consent.

Exclusion criteria:

Having liver or kidney diseases that contraindicate L-carnitine use. Children undergoing hemodialysis Children undergoing chemotherapy NPO patients who cannot start enteral nutrition

Age

From **1 month** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **38**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization is used to allocate participants to each study group randomly. For this study, six blocks of six participants each have been considered, with an equal number of participants assigned to the intervention and control groups within each block. The unit of randomization in this study is individual-based, and a random number table will be used for the allocation process.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The supplements and placebos were provided by Pars Behrouzan Jam Pharmaceutical Company and labeled with two-letter codes. All patients, researchers, data analysts, and outcome assessors will remain blinded to the contents of each label until the end of the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Mardani Azari Street, Khavaran Town, Zahra Mardani Azari Children's Educational and Research Center

City

Tabriz

Province

East Azarbaijan

Postal code

5367153121

Approval date

2024-12-02, 1403/09/12

Ethics committee reference number

IR.TBZMED.1403.753

Health conditions studied

1

Description of health condition studied

Critically ill children admitted to the PICU

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Serum C-Reactive Protein (CRP)

Timepoint

Before the start of the intervention and 7 days after the start of the intervention

Method of measurement
Blood test

2

Description
Serum ESR
Timepoint
Before the start of the intervention and 7 days after the start of the intervention
Method of measurement
Blood test

3

Description
Serum Total Antioxidant Capacity (TAC)
Timepoint
Before the start of the intervention and 7 days after the start of the intervention
Method of measurement
Blood test

4

Description
Serum Malondialdehyde (MDA)
Timepoint
Before the start of the intervention and 7 days after the start of the intervention
Method of measurement
Blood test

5

Description
Serum neutrophil to lymphocyte ratio (NLR)
Timepoint
Before the start of the intervention and 7 days after the start of the intervention
Method of measurement
Blood test

6

Description
Serum monocyte to lymphocyte ratio (MLR)
Timepoint
Before the start of the intervention and 7 days after the start of the intervention
Method of measurement
Blood test

7

Description
Serum platelet-to-lymphocyte ratio (PLR)
Timepoint
Before the start of the intervention and 7 days after the start of the intervention
Method of measurement
Blood test

8

Description
Superoxide Dismutase
Timepoint
Before the start of the intervention and 7 days after the start of the intervention
Method of measurement
Blood test

9

Description
Interleukin-6
Timepoint
Before the start of the intervention and 7 days after the start of the intervention
Method of measurement
Blood test

Secondary outcomes

1

Description
Total protein
Timepoint
Before the intervention and 7 days after the intervention
Method of measurement
Blood test

2

Description
Serum Albumin
Timepoint
Before the intervention and 7 days after the intervention
Method of measurement
Blood test

3

Description
Prognostic Nutritional Index (PNI)
Timepoint
Before the intervention and 7 days after the intervention
Method of measurement
serum albumin (g/L) + 0.005 × total lymphocyte count per micro liter of blood

4

Description
Systemic Immune-Inflammation Index (SII)
Timepoint
Before the intervention and 7 days after the intervention
Method of measurement
platelet count × neutrophil count / lymphocyte count

5

Description
Prognostic Index (PI)

Timepoint
Before the intervention and 7 days after the intervention
Method of measurement
based on C-reactive protein (CRP) and white blood cell (WBC) count as follows: PI = 2 when both CRP > 1 mg/dL and WBC > 11×10^9/L; PI = 1 when only one of these parameters is elevated; and PI = 0 when both parameters are within normal ranges

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Description
Glasgow Prognostic Score (GPS)
Timepoint
Before the intervention and 7 days after the intervention
Method of measurement
based on serum C-reactive protein (CRP) (g/L) and serum albumin (g/L). The score ranges from 0 to 2. A GPS of 0 will be assigned when CRP < 10 g/L and albumin > 35 g/L. A GPS of 1 will be assigned when either CRP > 10 g/L or albumin < 35 g/L is present. A GPS of 2 will be assigned when both CRP > 10 g/L and albumin < 35 g/L are present

Intervention groups

1

Description
Intervention group: 19 critically ill children admitted to the PICU will receive 50 to 100 mg/kg of liquid oral L-carnitine, produced by Pars Behrouzan Jam Company, along with tube feeding for 7 days.
Category
Treatment - Drugs

2

Description
Control group: 19 critically ill children admitted to the ICU will receive 50 to 100 mg/kg of distilled water, produced by Pars Behrouzan Jam Company, along with tube feeding for 7 days.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Zahra Mardani Azari Children's Educational and Research Center
Full name of responsible person
Maryam Behrooz
Street address
Zahra Mardani Azari Pediatric Research and Educational Center, Mardani Azari Street, Kheavaran Town.
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Phone
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Fax
Email
mm.behrooz@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Maryam Behrooz
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Zahra Mardani Azari Pediatric Research and Educational Center, Mardani Azari Street, Kheavaran Town.
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mm.behrooz@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Maryam Behrooz
Position
Nutrition specialist
Latest degree

Ph.D.

Other areas of specialty/work
Nutrition

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Person responsible for updating data

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Email
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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
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Not applicable

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