Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

A clinical trial to compare the effectiveness of citrulline supplementation with placebo on tolerance and complications of nutritional in patients admitted to the intensive care unit

Protocol summary

Study aim
To compare the effectiveness of citrulline supplementation with placebo on tolerance and complications of nutritional in patients admitted to the intensive care unit.

Design
This randomized and double-blind clinical trial with parallel and control groups will be conducted on 60 patients who will be randomly selected using the random number table.

Settings and conduct
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 citrulline supplementation 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: Aged between 18 and 75 years; non-participation in any other intervention research design. Exclusion criteria: Having citrulline allergies; pregnant women; the patient dies in the first 4 days of admission; patients who require of only parenteral nutrition.

Intervention groups
The intervention group will receive 3 mg citrulline supplementation (Daghigh Tajhiz Ario, Tehran, Iran) per day for 14 days. The control group will receive placebo (There is no citrulline in it, but it has the same color, taste, structure and shape as citrulline, produced by the research center of faculty of pharmacy, Mashhad University of Medical Sciences) per day for 14 days.

Main outcome variables
Evaluation and comparison of nutritional status, gastrointestinal bleeding, duration of hospital and intensive care unit stay, duration of mechanical ventilation and 28-day mortality rate.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220508054780N2**
Registration date: **2023-04-26, 1402/02/06**
Registration timing: **prospective**

Last update: **2023-04-26, 1402/02/06**
Update count: **0**

Registration date
2023-04-26, 1402/02/06

Registrant information

Name
Benyamin Fazli

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3802 2711

Email address
fazlib@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-22, 1402/03/01

Expected recruitment end date
2024-09-22, 1403/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A clinical trial to compare the effectiveness of citrulline supplementation with placebo on tolerance and complications of nutritional in patients admitted to the intensive care unit

Public title
The effectiveness of citrulline supplementation on tolerance and complications of nutritional in patients admitted to the intensive care unit

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Aged between 18 and 75 years Non-participation in any other intervention research design

Exclusion criteria:
Having citrulline allergies Pregnant women The patient dies in the first 4 days of admission Patient who require of only parenteral nutrition

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
1-2

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be simple randomly assigned to two groups using a random table type and opaque envelopes will be used for concealment.

Blinding (investigator's opinion)
Double blinded

Blinding description
The participants and responsible for data collection are blind to group allocation and the type of intervention.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences

Street address
Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

City
Mashhad

Province
Razavi Khorasan

Postal code
9195965919

Approval date
2023-01-09, 1401/10/19

Ethics committee reference number
IR.MUMS.IRH.REC.1401.054

Health conditions studied

1

Description of health condition studied
Tolerance and complications of nutritional in patients admitted to the intensive care unit

ICD-10 code
Y57.8

ICD-10 code description
Other drugs and medicaments

Primary outcomes

1

Description
Nutritional status

Timepoint
Before, 2, 7 and 14 days after intervention

Method of measurement
Using by NUTRIC score questionnaire

2

Description
Gastrointestinal bleeding

Timepoint
Before, 2, 7 and 14 days after intervention

Method of measurement
Using by the sequential organ failure assessment (SOFA) score

Secondary outcomes

1

Description
Duration of hospital and intensive care unit stay

Timepoint
From the time of admission to the end of the intervention

Method of measurement
Based on the number of days the patient was hospitalized

2

Description
Duration of mechanical ventilation
Timepoint
From the time of admission to the end of the intervention
Method of measurement
The rate of using of patient the ventilator

3

Description
28-day mortality rate
Timepoint
28 days after intervention
Method of measurement
Based on days after intervention

Intervention groups

1

Description
Intervention group: The intervention group will receive 3 mg citrulline supplementation (Daghigh Tajhiz Ario, Tehran, Iran) per day for 14 days.
Category
Treatment - Drugs

2

Description
Control group: The control group will receive placebo (There is no citrulline in it, but it has the same color, taste, structure and shape as citrulline, produced by the research center of faculty of pharmacy, Mashhad University of Medical Sciences) per day for 14 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Benyamin Fazli
Street address
Imam Reza Hospital, Imam Reza Square
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Mashhad
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9137913316
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fazlib@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street
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Postal code
9138813944
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+98 51 3841 1538
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vcresearch@mums.ac.ir
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
Benyamin Fazli
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Imam Reza Hospital, Imam Reza Square
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Person responsible for scientific inquiries

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Full name of responsible person
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Position
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Person responsible for updating data

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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
Not applicable

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The research data obtained from the main outcomes of the study can be shared freely as 'open data'.

When the data will become available and for how long
6 months after publishing the results

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

From where data/document is obtainable
Benyamin Fazli provides the data analysis to the applicants via email: fazlib@mums.ac.ir.

What processes are involved for a request to access data/document
Applicants can send emails to him and receive a response within a week.

Comments