

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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9137913316

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Email

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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Mashhad

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Razavi Khorasan

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9138813944

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+98 51 3841 1538

Email

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

Contact

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Mashhad University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

Contact

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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