# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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
**City**
Mashhad
**Province**
Razavi Khorasan
**Postal code**
9137913316
**Phone**
+98 51 3802 2711
**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
**City**
Mashhad
**Province**
Razavi Khorasan
**Postal code**
9138813944
**Phone**
+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
**City**
Mashhad
**Province**
Razavi Khorasan
**Postal code**

9137913316

**Phone**
+98 51 3802 2711

**Email**
fazlib@mums.ac.ir

## Person responsible for scientific 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

**City**
Mashhad

**Province**
Razavi Khorasan

**Postal code**
9137913316

**Phone**
+98 51 3802 2711

**Email**
fazlib@mums.ac.ir

## Person responsible for updating data

**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

**City**
Mashhad

**Province**
Razavi Khorasan

**Postal code**
9137913316

**Phone**
+98 51 3802 2711

**Email**
fazlib@mums.ac.ir

## 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**