Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of high-dose protein compared to conventional protein on intestinal permeability, disease severity, and mortality in critically ill patients admitted to the intensive care units.

Protocol summary

Study aim

Effect of high-dose protein compared to conventional protein on intestinal permeability, disease severity, and mortality in critically ill patients admitted to the intensive care units.

Design

88 critically ill patients will be divided into two groups of 44: intervention and control, using a randomized block design.

Settings and conduct

The study subjects will be selected from 88 critically ill patients at Hazrat Rasoul Akram Hospital in Tehran. The intervention group will receive enteral nutrition with high protein content (1.6 g/kg/day) and the control group will receive enteral nutrition with normal protein content (1.2 g/kg/day). During the intervention, zenulin levels will be assessed on days 0, 5, and 10. The SOFA, APACHE II, and NUTRIC questionnaires will also be assessed. Mortality rates will be calculated at 30 days and 60 days from the start of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- ages 18 to 65 (both sexes) 2- At least 24 hours have passed since admission to the intensive care unit. 3- At least 1 day has passed since the patient received enteral feeding. 4- The patient is stable in hemodynamics. 5- At least 60% of the protein intake is provided by enteral feeding. 6- Willingness to cooperate and sign the informed consent Exclusion criteria: 1- Death or discharge before 4th day 2- Consuming glutamine supplementation 3- NPO more than 4 days 4- Contraindication to EN 5- Unwillingness to cooperate in the project

Intervention groups

(1.6 g/kg/day) in the intervention group and (1.2 g/kg/day) in the control group

Main outcome variables

Zonulin levels and intestinal permeability; APACHE II questionnaire; SFOA questionnaire; NUTRIC questionnaire; 30-day and 60-day mortality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241129063891N1**
Registration date: **2024-12-11, 1403/09/21**
Registration timing: **prospective**

Last update: **2025-07-11, 1404/04/20**
Update count: **1**

Registration date

2024-12-11, 1403/09/21

Registrant information

Name

Shonaz Ahmadikhatir

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3800 2359

Email address

sh_khatir@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-03-02, 1403/12/12

Expected recruitment end date

2025-09-21, 1404/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of high-dose protein compared to conventional protein on intestinal permeability, disease severity, and mortality in critically ill patients admitted to the intensive care units.

Public title

Effect of high-dose protein compared to conventional protein on intestinal permeability, disease severity, and mortality in critically ill patients admitted to the intensive care units.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Ages 18 to 65 (both sexes) At least 24 hours have passed since admission to the intensive care unit. At least 1 day has passed since the patient received enteral feeding. The patient is stable in hemodynamics At least 60% of the protein intake is provided by enteral feeding. Willingness to cooperate and sign the informed consent.

Exclusion criteria:

Death or discharge before 4th day consuming Glutamine supplementation NPO more than 4 days Contraindication to EN Unwillingness to cooperate in the project

Age

From **18 years** old to **65 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: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

Random permutation blocks

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, principal investigator, healthcare providers

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

Shahid Fakouri Blvd, Mashhad University of Medical Sciences

City

Mashhad

Province

Razavi Khorasan

Postal code

91778-99191

Approval date

2024-11-17, 1403/08/27

Ethics committee reference number

IR.MUMS.REC.1403.298

Health conditions studied

1

Description of health condition studied

critically ill patients admitted to the intensive care units

ICD-10 code

R69

ICD-10 code description

Illness, unspecified

Primary outcomes

1

Description

Zonulin levels and intestinal permeability are increased in critically ill patients.

Timepoint

zonulin levels will be assessed before the start of the intervention and on days 5 and 10.

Method of measurement

Zonulin (ng/mL) will be measured from serum samples using a human zonulin ELISA kit with a sandwich ELISA method.

2

Description

Mortality

Timepoint

SOFA Questionnaire

Method of measurement

Every other day - Scores range from 0 to 24 - higher values indicate organ dysfunction and a poor prognosis.

3

Description

Disease Severity

Timepoint
APACHE questionnaire
Method of measurement
first day of admission - score between 1 and 71 - score above 34 show 85% mortality

4

Description
Nutritional risk assessment
Timepoint
The first 24 hours after admission to the ICU
Method of measurement
mNUTRIC score - 0 to 9 points - scores ≥4 indicate nutritional risk and are considered high risk and scores <4 indicate low nutritional risk

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: High-protein enteral nutrition (1.6 g/kg/day)
Category
Treatment - Other

2

Description
Control group: Enteral nutrition with conventional protein intake (1.2 g/kg/day)
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Rasool Akram Hospital
Full name of responsible person
Omid Moradimoghaddam
Street address
Sattarkhan Ave. - Niayesh Street - Hazrat Rasool Akram Hospital
City
Tehran
Province
Tehran
Postal code
14456-13131
Phone
+98 21 8670 1021
Email
moradimoghadam@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohammad Safarian
Street address
Shahid Fakouri Blvd, Mashhad University of Medical Sciences
City
Mashhad
Province
Razavi Khorasan
Postal code
91778-99191
Phone
+98 51 3800 2359
Email
Safarianm@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
Shonaz Ahmhmadikhatir
Position
PhD Student
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
Shahid Fakouri Blvd, Mashhad University of Medical Sciences
City
Mashhad
Province
Razavi Khorasan
Postal code

91778-99191

Phone
+98 51 3800 2359

Email
Sh_khatir@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Mohammad Safarian

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
Shahid Fakouri Blvd, Mashhad University of Medical Sciences

City
Mashhad

Province
Razavi Khorasan

Postal code
91778-99191

Phone
+98 51 3800 2359

Email
Safarianm@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Pardis Irandoost

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
Hemmat Highway, next to Milad Tower, Iran University of Medical Sciences

City
Tehran

Province
Tehran

Postal code
14496-14535

Phone
+98 21 86701

Email
pardis_irandoost@yahoo.com

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

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

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

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