Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of high protein nutritional support in comparison to nutritional support with regular protein intake in intensive care unit patients: a double-blind randomized clinical trial

Protocol summary

Study aim
Evaluation of the effect of high-protein nutritional support compared to conventional-protein nutritional support in critically ill patients admitted to the intensive care unit

Design
This parallel, randomized, double-blind clinical trial was conducted on 60 ICU patients at Imam Reza Hospital, Mashhad, Iran. Participants were randomly allocated (1:1) using stratified block randomization (by age and sex; block size of 4). An independent statistician generated the allocation sequence using a random number table, and assignments were concealed in opaque, sequentially numbered envelopes, opened only after confirming eligibility.

Settings and conduct
Eligible ICU patients at Imam Reza Hospital will be enrolled after specialist assessment. Weight, height (via ulna length), and MUAC will be measured. Demographic, clinical, and laboratory data will be recorded. High- and conventional-protein BTF formulas (2.2 vs. 1.0 g/kg/day) will be prepared in identical containers (Formula A/B) and will be visually indistinguishable. Patients will receive gavage feeding every 3 hours, 7 times daily, for 12 days.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18–80 years, ICU admission with ≥72 hours of mechanical ventilation, legal consent or judicial approval, Enteral feeding possible within 48 hours, No participation in other interventional studies. Exclusion criteria: Pregnancy or lactation, Exclusive need for parenteral nutrition, History of liver cirrhosis or end-stage renal disease, Inability to tolerate enteral feeding, Intervention duration <4 days, Frequent transfusions or physician-determined ineligibility.

Intervention groups
Intervention: 2.2 g/kg of Karen's Iso Whey protein per day Control: 1 g/kg of Karen's Iso Whey protein per day

Main outcome variables
60 days mortality

General information

Reason for update
Correction of trial information based on the latest protocol version

Acronym

IRCT registration information
IRCT registration number: **IRCT20180619040151N4**
Registration date: **2019-11-07, 1398/08/16**
Registration timing: **registered_while_recruiting**

Last update: **2025-07-15, 1404/04/24**
Update count: **1**

Registration date
2019-11-07, 1398/08/16

Registrant information

Name
Abdolreza Norouzy

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3800 2382

Email address
norouzya@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-10-11, 1398/07/19

Expected recruitment end date
2020-07-09, 1399/04/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of high protein nutritional support in comparison to nutritional support with regular protein intake in intensive care unit patients: a double-blind randomized clinical trial

Public title

Determination of the effect of high protein nutritional support in comparison to nutritional support with common protein in intensive care unit patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18-80 years old Patients who have been ventilated for at least the first 72 hours of admission Completion of informed consent form in the first stage of legal guardianship in case of failure in this field to the judge. Ability to enteral feed in the first 24 to 48 hours of admission. Lack of participation in any other interventional research project. ICU admission

Exclusion criteria:

Pregnant or lactation Patients require only parenteral nutrition History of diseases such as hepatocirrhosis and End-stage renal disease. inability to tolerate EN receipt of the study intervention for fewer than four days frequent need for blood transfusions; or physician discretion deeming the patient unsuitable for participation.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

After selecting 60 patients based on inclusion criteria, they will be divided into two groups of intervention or control through stratified block randomization by using the numbered, sealed and stapled envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

In the present study, both patients and outcome assessors will be blinded throughout the study.

Placebo

Not 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

Mashhad University of Medical Sciences, Mashhad, Park Square.

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2018-12-11, 1397/09/20

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1397.543

Health conditions studied

1

Description of health condition studied

Critical ill patients

ICD-10 code

Z00.01

ICD-10 code description

Encounter for general adult medical examination with abnormal findings

Primary outcomes

1

Description

mortality

Timepoint

mortality in the intensive care unit, days 28 and 60 after intaking protein

Method of measurement

If the patient is discharged from the intensive care unit, the patient will be contacted by telephone.

Secondary outcomes

1

Description

Nutrition Risk in the Critically Ill (NUTRIC) Score

Timepoint

Before intervention

Method of measurement

Nutrition Risk in the Critically Ill (NUTRIC) Score

2

Description

Acute Physiology and Chronic Health Evaluation (APACHE II) score changes

Timepoint

Before intervention

Method of measurement

Acute Physiology and Chronic Health Evaluation (APACHE II) score

3

Description

Sequential Organ Failure Assessment (SOFA) score

Timepoint

Before intervention, day 3, 5, 7, 9 and 11

Method of measurement

Sequential Organ Failure Assessment (SOFA) Score

4

Description

SARC-F Screen for Sarcopenia changes

Timepoint

Before intervention

Method of measurement

SARC-F Score

5

Description

Clinical Frailty Scale changes

Timepoint

Before intervention

Method of measurement

Clinical Frailty Scale score

Intervention groups

1

Description

The intervention group received 2.2 g/kg/day of Karen's Iso Whey protein via gavage feeding for 12 days. Surplus protein was primarily provided through enteral nutrition (BTF), with parenteral amino acids used only if enteral intake was insufficient.

Category

N/A

2

Description

Control group: 1 g / kg of Karen's Iso Whey protein per day by gavage feeding method in 12 days. (This amount of surplus protein will be given with BTF is given to patients.)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emamreza hospital

Full name of responsible person

Alireza Sedaghat

Street address

Ebne Sina Ave

City

Mashhad

Province

Razavi Khorasan

Postal code

99191-91778

Phone

+98 51 3800 2429

Email

SedaghatAR@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

Mashhad University of Medical Sciences, 18 Daneshgah Ave. Daneshgah Ave

City

Mashhad

Province

South Khorasan

Postal code

9196773117

Phone

+98 51 1882 3255

Fax

+98 51 1882 3251

Email

tafaghodim@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
Abdolreza Norouzy

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Nutrition

Street address
Azadi-squre

City
Mashhad

Province
Razavi Khorasan

Postal code
99191-91778

Phone
+98 51 3800 2382

Fax
+98 51 3800 2421

Email
norouzya@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Abdolreza Norouzy

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Nutrition

Street address
Azadi-squre

City
Mashhad

Province
Razavi Khorasan

Postal code
99191-91778

Phone
+98 51 3800 2382

Fax
+98 51 3800 2421

Email
norouzya@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Mohaddeseh Badpeyma

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

Street address
Bahonar Blvd

City
Mashhad

Province
Razavi Khorasan

Postal code
91779-48988

Phone
+98 51 3882 8299

Email
Badpimamh961@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

Study Protocol
No - There is not 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