Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of different doses of protein on nitrogen balance and clinical outcomes in intensive care unit patients

Protocol summary

Study aim
The effect of different doses of protein on nitrogen balance and clinical outcomes in intensive care unit patients

Design
The design of this study is a parallel clinical trial in phase 2-3. It has a control group where patients will be assigned to study groups by block randomization method. Blinding is double-blind and the sample size is 60 patients.

Settings and conduct
The aim of this study is the effect of different doses of protein with 2.6, 2, and 1.3 g/kg on nitrogen balance and clinical outcomes of patients admitted to the intensive care unit of Rasoul Akram Hospital affiliated to Iran University of Medical Sciences. Both the patients and the evaluators of thickness of muscle will be blinding of the amount of dose received by the participants in the study groups, finally the type of blinding is double blinded.

Participants/Inclusion and exclusion criteria
Age over 18 years and at least 11 days of hospitalization in the intensive care unit are the included criteria. Non-Include criteria are Liver or kidney failure, dialysis, anuric, oliguric, or having diarrhea.

Intervention groups
In this study, we will have three groups of patients giving different doses of protein.Patients giving doses of 2.6 and 2 g/kg will be intervention groups and patients giving dose of 1.3 g/kg will be control groups.

Main outcome variables
Nitrogen balance; thickness of biceps brachii muscle; duration of use of mechanical ventilation; the duration of the patient's hospitalization in the intensive care unit; the number of positive cultures of nosocomial infection; mortality.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170903036041N6**
Registration date: **2023-07-06, 1402/04/15**
Registration timing: **prospective**

Last update: **2023-07-06, 1402/04/15**
Update count: **0**

Registration date
2023-07-06, 1402/04/15

Registrant information

Name
Omid Moradi Moghadam

Name of organization / entity
Iran University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 21 6653 9233

Email address
moradimoghadam.o@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-08, 1402/04/17

Expected recruitment end date
2023-10-22, 1402/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of different doses of protein on nitrogen balance and clinical outcomes in intensive care unit

patients

Public title
The effect of protein with different doses on nitrogen balance
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years At least 11 days of hospitalization in the intensive care unit
Exclusion criteria:
Death or discharge before 11 days of hospitalization in the intensive care unit Patients with liver, kidney and dialysis failure Anuric, oliguric or diarrhea patients Patients with high drain secretions A glomerular filtration rate less than 50
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The block randomization method was used in this study. The size of the blocks is considered to be six and will be selected randomly so that it is not predictable to the participants based on the blocks. First, we will receive using Random Allocation software and by determining the sample size, the number of groups, the type of randomization and is random the order of the blocks in the software output and will be shown in the software output of groups with letters A, B and C. Then, after selecting each patient based on the inclusion and non-inclusion criteria, the project manager will be informed and he will tell the type of intervention of that patient based on the order of inclusion of patients and compliance with the number mentioned in the randomization output.
Blinding (investigator's opinion)
Double blinded
Blinding description
We will inform the supervisor after selecting each patient for the study and they are based on the randomized output of the randomization software and its matching to the patient's number the interventions will be sent in a form that is not known to the patients, prescriptive, and evaluator of the outcomes. Blinding process in this study is double blinded. Participants in the study will be blinded of interventions also the physicians will be blinded of the type of interventions received by the participants when they evaluated the outcome.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran university of Medical Sciences
Street address
Iran University of Medical Sciences, Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2023-06-03, 1402/03/13
Ethics committee reference number
IR.IUMS.FMD.REC.1402.120

Health conditions studied

1

Description of health condition studied
Patients admitted to the intensive care unit
ICD-10 code
Z01.8
ICD-10 code description
Encounter for other specified special examinations

Primary outcomes

1

Description
Nitrogen balance
Timepoint
Urine 24 hours admission time, time to reach the protein target and the 11 day study
Method of measurement
Based on the measurement of urea concentration in urine

2

Description
Thickness of biceps brachii muscle
Timepoint
Beginning and day 11 of the study
Method of measurement
Sonography

Secondary outcomes

1

Description
Duration of use of mechanical ventilation
Timepoint
Duration of hospitalization
Method of measurement
Visit the patient/patients' files

2

Description
The duration of the patient's hospitalization in the intensive care unit
Timepoint
The total number of days the patient is in the ward
Method of measurement
Patients' files

3

Description
The number of positive cultures of nosocomial infection
Timepoint
The duration of the patient's hospitalization in the intensive care unit
Method of measurement
The number of positive culture results

4

Description
Mortality
Timepoint
28 days after receiving interventions
Method of measurement
The discharge status of the patient as well as telephone follow-up 28 days after receiving the intervention

Intervention groups

1

Description
The first intervention group: protein with a dose of 2.6 grams per kilogram of body weight daily for seven days, produced by Karen Pharmaceutical Company
Category
Treatment - Drugs

2

Description
The second intervention group: protein with a dose of 2 grams per kilogram of body weight daily for seven days, produced by Karen Pharmaceutical Company
Category
Treatment - Drugs

3

Description
Control group: protein with a dose of 1.3 grams per kilogram of body weight daily for seven days, produced by Karen Pharmaceutical Company
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul Akram hospital
Full name of responsible person
Omid Moradimoghadam
Street address
Rasoul Akram hospital, Niyayesh St, Sattarkhan St
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6653 9260
Email
moradimoghadam.o@iums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Reza Falak
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 5503
Email
research@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Rashin Taghizadeh
Position
Fellowship
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Rasoul Akram hospital, Niyayesh St, Sattarkhan St
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6653 9233
Email
taghizadehrashin@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Omid Moradimoghadam
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Rasoul Akram hospital, Niyayesh St, Sattarkhan St
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6653 9260
Email
moradimoghadam.o@iums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Rashin Taghizadeh
Position
Fellowship
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Rasoul Akram hospital, Niyayesh St, Sattarkhan St
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6653 9260
Email
taghizadehrashin@gmail.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
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
Yes - There is 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
Title and more details about the data/document
Finding of the study, demographic data of participants in the study, in addition to descriptive and analytical analysis of variables.
When the data will become available and for how long
Availability six months after the end of study.
To whom data/document is available
Critical care fellowships, anesthesiologists, internists.
Under which criteria data/document could be used
Requests may be made by organizations, journals or project supervisors. These requests will be read by the research team under the supervision of a university representative, and if the requests are reasonable, relevant de-identified data will be sent. This request may

be some results of biomarkers or codes performed for data analysis.

From where data/document is obtainable

The initial request can be sent to the email of the people who are in the scientific and general response section of the trial (taghizadehrashin@gmail.com, moradimoghadam.o@iums.ac.ir). Applicants can also refer to the Research Vice-Chancellor of Iran University of Medical Sciences located on Hemet Highway or the Iran Clinical Trial Center located in the Central Library of Iran University of Medical Sciences.

What processes are involved for a request to access data/document

After the institution agrees to send data for requests, depending on whether the requester is inside the country or abroad, and also according to the type of requested data, the time to respond to the requests will be different. Finally, no request will take more than one month.

Comments