

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 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

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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

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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

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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

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Omid Moradimoghadam

Position

Associate professor

Latest degree

Subspecialist

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Person responsible for updating data**Contact****Name of organization / entity**

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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