

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of nutritional support provided by a nutritionist in improving the outcomes of patients admitted to the intensive care unit (ICU)

Protocol summary

Study aim

The main objective: Evaluation of the effect of nutritional support provided by nutritionist in improving the outcomes of patients hospitalized in the intensive care unit

Design

The current study is a non-blinded randomized clinical trial with parallel groups that is conducted on 100 hospitalized patients.

Settings and conduct

Patients hospitalized in the intensive care unit of Firouzgar Hospital, Tehran, who are eligible to enter the study, will be randomly divided into intervention and control groups without blinding.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients over 18 years of age hospitalized in surgical and general ICUs who are estimated to have a hospitalization period of more than 3 days are included in the plan. Exclusion criteria: GCS less than 8, C score for Child Pugh, pregnancy, Dialysis Failure to start nutritional support within the first 48 hours

Intervention groups

Intervention group: There are patients who receive nutritional support including enteral or intravenous nutrition by a nutritionist. Enteral feeding will be done with gavage powders from Karen company, parenteral feeding will be done with intralipid and amino acid solutions from Fresenius Kaby, and the amount to be consumed will be determined based on the patient's weight and other conditions. Control group: There are patients who will receive nutritional support including enteral or intravenous nutrition from other medical services (surgeon, internist, etc.).

Main outcome variables

Length of stay in ICU, Duration of ventilator use or need, Occurring new pressure ulcers, The need for surgery or

unplanned medical interventions, Occurrence of kidney disorders, Occurrence of liver disorders, Occurrence of infectious complications 48 hours after the start of the intervention, death

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200405046951N2**

Registration date: **2023-01-28, 1401/11/08**

Registration timing: **registered_while_recruiting**

Last update: **2023-01-28, 1401/11/08**

Update count: **0**

Registration date

2023-01-28, 1401/11/08

Registrant information

Name

Azadeh Mottaghi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8603 6080

Email address

mottaghi.a@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-05-20, 1402/02/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of nutritional support provided by a nutritionist in improving the outcomes of patients admitted to the intensive care unit (ICU)

Public title
Investigating the effect of nutritional support on the recovery of patients admitted to the intensive care unit

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years Hospitalization period of more than 3 days in the intensive care unit
Exclusion criteria:
Patients with extensive head trauma (GCS less than 8) Severe liver disease (score C for Child Pugh) Treated with dialysis Patients who are admitted to the ICU for open-heart surgery are not included in the study because the duration of their hospitalization depends on several underlying factors. Pregnancy Patients who have not received nutritional support 48 hours after being admitted to the ICU for some reason will not be included in the plan

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, we will use the limited randomization method of the block randomization type. The randomization tool is also used from random sequence generation software (<https://www.graphpad.com/quickcalcs/>), which, in addition to simple randomization, is capable of generating random sequence by block method (10 blocks of 10). For concealment, we use random allocation concealment, which refers to the method used to perform a random sequence on study participants, in such a way that the allocated group is not known before individual allocation. By using sealed opaque letter envelopes with a random sequence, in this method, each of the random sequences created is recorded on a card and the cards are placed inside the letter envelopes in order. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box. At the time of starting the registration of

participants, based on the order in which eligible participants entered the study, one of the envelopes will be opened and the assigned group of that participant will be revealed.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat highway

City

Tehran

Province

Tehran

Postal code

1593716615

Approval date

2022-08-09, 1401/05/18

Ethics committee reference number

IR.IUMS.REC.1401.429

Health conditions studied

1

Description of health condition studied

Critically ill patient

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Length of stay in ICU

Timepoint

before the intervention and when the patient is discharged from the intensive care unit

Method of measurement

Counting days of hospitalization

Secondary outcomes

1

Description

Duration of ventilator use or need

Timepoint

During the intervention period (the duration of the patient's hospitalization in the intensive care unit)

Method of measurement

Counting days of intervention (Event Registration Questionnaire)

2

Description

mortality rate

Timepoint

During the intervention period (the duration of the patient's hospitalization in the intensive care unit)

Method of measurement

Event registration (Event Registration Questionnaire)

3

Description

Occurring new pressure ulcers

Timepoint

During the intervention period (the duration of the patient's hospitalization in the intensive care unit)

Method of measurement

Event registration (Event Registration Questionnaire)

4

Description

The need for surgery or unplanned medical interventions

Timepoint

During the intervention period (the duration of the patient's hospitalization in the intensive care unit)

Method of measurement

Event registration (Event Registration Questionnaire)

5

Description

Occurrence of kidney disorders with the definition of creatinine more than 1.2 mg/dL or the need for dialysis

Timepoint

During the intervention period (the duration of the patient's hospitalization in the intensive care unit)

Method of measurement

Event registration (Event Registration Questionnaire)

6

Description

The occurrence of liver disorders with the definition of bilirubin more than 1.2 mg/dL

Timepoint

During the intervention period (the duration of the patient's hospitalization in the intensive care unit)

Method of measurement

Event registration (Event Registration Questionnaire)

7

Description

Incidence of infectious complications according to the definition of infection in the ICU of the International Sepsis Association (ventilator-associated pneumonia, bacteremia, urinary tract infections, wound infections, abdominal infections) 48 hours after the start of the intervention

Timepoint

During the intervention period (the duration of the patient's hospitalization in the intensive care unit)

Method of measurement

Event registration (Event Registration Questionnaire)

Intervention groups

1

Description

Intervention group: Patients admitted to the intensive care unit are under nutritional support including enteral or intravenous nutrition by a nutritionist. Enteral feeding will be done with gavage powders from Karen company, parenteral feeding will be done with intralipid and amino acid solutions from Fresenius Kaby, and the amount to be consumed will be determined based on the patient's weight and other conditions.

Category

Treatment - Other

2

Description

Control group: patients hospitalized in the intensive care unit who will receive nutritional support including enteral or intravenous nutrition from other medical services (surgeon, internist, etc.).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Firouzgar Hospital

Full name of responsible person

Dr. Azadeh Mottaghi

Street address

No. 10, Firoozeh alley, Vali Asr Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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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

Dr. Azadeh Mottaghi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Person responsible for updating data

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Name of organization / entity

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

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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

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