Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Nov 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, parentral 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)

Phone

+98 21 8603 6080

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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, parentral 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
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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
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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