Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of personalized parenteral nutrition on Intensive care unit (ICU) patients

Protocol summary

Study aim
Determination of the effect of personalized parenteral nutrition on ICU patients

Design
Randomized clinical trial,2-blind trial,60 ICU patients candidate for parenteral nutrition, Intervention and control groups through randomization,30 patients as intervention group & 30 patients as control group.

Settings and conduct
We attend at ICU of Razi hospital in Rasht and complete consent form, information will be required using questionnaires: Medical history, Anthropometric measurement, Dietary intake, Biochemical indices (at baseline and after 14 days). This is a Double-blind trial study, which intervention and control groups are blinded to intervention assignment and nurses who assess and collect data on outcome, are blinded to groups' assignment.

Participants/Inclusion and exclusion criteria
Study will be done in the Rasht Razi hospital.60 ICU patients who are candidate for parenteral nutrition,will be selected and enter to the study in the intervention and control groups through simple randomized selection.Inclusion criteria:Informed consent,need to parenteral nutrition at least 24-h of hospitalization and exclusion criteria:no tendency,no parenteral nutrition indication for more than 1 week,death,not having severe or middle malnutrition.

Intervention groups
We avoid feeding the lipid to intervention group in the first of hospitalization. Required protein will be calculated upon patient's status and determined by required percent of amino acids & Dextrose. We use daily relevant vials for providing vitamins & minerals. Control group daily receive low calorie of intra venous diet(800-1000 calories) upon hospital's routine. We usually administer Dextrose every day, providing 70% and administer Aminoven or Intralipid every other day, providing 30% of patient's calorie.All of measurements repeated after one week.

Main outcome variables
Urea, Creatinine, CRP, ICU hospitalization, Survival rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151226025699N4**
Registration date: **2020-06-03, 1399/03/14**
Registration timing: **prospective**

Last update: **2020-06-03, 1399/03/14**
Update count: **0**

Registration date
2020-06-03, 1399/03/14

Registrant information

Name
Saeid Doaei

Name of organization / entity
National Nutrition and Food Technology Research Institute

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-04, 1399/03/15

Expected recruitment end date
2020-06-18, 1399/03/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of personalized parenteral nutrition on Intensive care unit (ICU) patients

Public title

The effect of parenteral nutrition on ICU patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Consent to participation Need to parenteral nutrition At least 24-h of hospitalization

Exclusion criteria:

Having no indication for parenteral nutrition for more than 1 week Unstable hemodynamic conditions

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients of ICU are assigned to the intervention and control groups through simple individualized randomization by online software (randomizer.org).

Blinding (investigator's opinion)

Double blinded

Blinding description

The subjects (both the case and control groups) are blinded to intervention assignment. Also, nurses who assess and collect data on outcome, are blinded to groups' assignment.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Cancer research center of Shahid beheshti University of Medical Sciences

Street address

Tehran, Tajrish square, Tajrish martys hospital,Cancer research center

City

Tajrish

Province

Tehran

Postal code

1985717413

Approval date

2019-11-12, 1398/08/21

Ethics committee reference number

IR.SBMU.CRC.REC.1398.015

Health conditions studied

1

Description of health condition studied

Gastrointestinal hemorrhage

ICD-10 code

K92.2

ICD-10 code description

Gastrointestinal hemorrhage, unspecified

Primary outcomes

1

Description

Urea

Timepoint

Baseline, 14-day after intervention

Method of measurement

using standard kits and the researchers gather these information from the lab test section of the ICU sheets.

2

Description

Creatinine

Timepoint

Baseline, 14-day after intervention

Method of measurement

using standard kits and the researchers gather these information from the lab test section of the ICU sheets.

3

Description

C reactive protein (CRP)

Timepoint

Baseline, 14-day after intervention

Method of measurement

using standard kits and the researchers gather these information from the lab test section of the ICU sheets.

4

Description

Serum albumin

Timepoint

Baseline, 14-day after intervention

Method of measurement

using standard kits and the researchers gather these information from the lab test section of the ICU sheets.

Secondary outcomes

1

Description

ICU hospitalization

Timepoint

Baseline, 14-day after intervention

Method of measurement

Patients documents

2

Description

Survival rate

Timepoint

During 14-day intervention

Method of measurement

Patients documents

3

Description

Weight

Timepoint

During 14-day intervention

Method of measurement

This anthropometric indicator will be gathered from the patients records.

4

Description

Body mass index (BMI)

Timepoint

During 14-day intervention

Method of measurement

This anthropometric indicator will be gathered from the patients records.

5

Description

Malnutrition status

Timepoint

During 14-day intervention

Method of measurement

It will be evaluated by weight & BMI criteria and by the level of serum albumin. We also use the Nutritional Risk Screening (NRS 2002) criterion for more evaluation.

Intervention groups

1

Description

After the gain of real weight and evaluation of disease status and chemistry results, the amount of required calorie will be estimated according to the ASPEN guidelines and then, the appropriate diet will be designed. We avoid to feeding the lipid in the first of hospitalization. The required protein will be calculated according to the patient's status and determined by the required percent of amino acids and Dextrose. We also will use the daily relevant vials for providing the vitamins and required minerals. Finally, we will insert the diet with relevant advises in to the conference form and deliver to the relevant specialist doctor for final acceptance.

Category

Treatment - Drugs

2

Description

Control group will daily receive low calorie of parenteral diet, including 800 to 1000 calories according to the hospital's routine. We usually administer Dextrose every day, which provide 70% of patient's calorie and administer Aminoven or Intralipid every other day, which provide 30% of patient's calorie. All of measurements repeated after one week.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Siamak Rimaz

Street address

RaziSardare Jangal Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Pr. Mohammad Esmaeil Akbari

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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
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
50
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

2

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Dr. Arsalan salari
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Rasht university of medical sciences
Proportion provided by this source
50
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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Pr. Mohammad Esmaeil Akbari
Position
Super-specialist of Endocrine and Cancer surgery
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Others
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Person responsible for updating data

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Other areas of specialty/work
Nutrition

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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
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