

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

comparative clinical outcome in Hypocaloric vs. Fullcaloric Enteral feeding during the first week of Hospitalization in Intensive Care Unite Patients

Protocol summary

Study aim

comparative clinical outcome in Hypocaloric vs. Fullcaloric Enteral feeding during the first week of Hospitalization in Intensive Care Unite Patients

Design

The present study will be conducted on 126 patients admitted to Shahid Kamyab (Emdadi Hospital) intensive care unit. patients will be under randomly assigned Stratified blocked randomization (RCT) and will divide to two groups, hypocaloric and fullcaloric diet.

Settings and conduct

The present study is a Randomized double-blind controlled trial on 126 patients admitted to Shahid Kamyab (Emdadi Hospital) intensive care unit

Participants/Inclusion and exclusion criteria

Entrance criteria include: adult patients, 18 to 65 y old that expected to Hospitalization in Intensive Care Unite Patients for at least 94 hours and cannot eat sufficiently
exclusion criteria include: mechanical ventilation and body mass index (BMI) <18

Intervention groups

Patients are divided in two groups (63 Patients in each group). after initiation of hemodynamic status during the first 24-48 hours of onset of intestinal nutritional support, patients will be under bolus enteral nutrition each three hours (6 times per 24 hours). In the hypocaloric diet group, 40% of calculated calorie in the first 24-48 hours of admission is given and is given in 100% of a week, and full calorie diet group will receive 100-80% of calculated calorie in the first 24-48 hours of admission

Main outcome variables

Primary outcomes: Anthropometric and metabolic factors. Secondary outcomes: Hospital length of stay, 28 day mortality, severity of disease, Duration of mechanical ventilation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120525009856N6**

Registration date: **2018-03-26, 1397/01/06**

Registration timing: **prospective**

Last update: **2018-03-26, 1397/01/06**

Update count: **0**

Registration date

2018-03-26, 1397/01/06

Registrant information

Name

Yahya Pasdar

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1828 1991

Email address

yahya.pasdar@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-30, 1397/01/10

Expected recruitment end date

2018-07-06, 1397/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparative clinical outcome in Hypocaloric vs. Fullcaloric Enteral feeding during the first week of Hospitalization in Intensive Care Unite Patients

Public title

The effect of calorie intake on Intensive Care Unite patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with expected length of hospitalization in Intensive Care Unite for at least 94 hours adult patients, 18 to 65 y old cannot eat sufficiently

Exclusion criteria:

body mass index (BMI) less than 18.5 mechanical ventilation

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, patients will be divided into two groups of hypocaloric and full-calorie diet by using Stratified blocked randomization, so that two groups will not have a significant difference in terms of gender, age, body mass index and severity of illness.

Blinding (investigator's opinion)

Double blinded

Blinding description

Double-blinded method will be used in order to prevent incidence of information bias, in such a way that after calculating required energy for patient, a code will be given to the subject. Afterwards, the patient will be enter into one of the two groups of intervention and control group, based on the attained code through randomized classified method.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Deputy of Research and Technology, Building No. 2 of Kermanshah University of Medical Sciences, Naft Square, Shahid Beheshti blvd

City

Kermanshah

Province

Kermanshah

Postal code

6719851351

Approval date

2018-02-14, 1396/11/25

Ethics committee reference number

IR.KUMS.REC.1396.624

Health conditions studied

1

Description of health condition studied

Patients of intensive care unit

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Aspartate amino transferase

Timepoint

Before intervention, after intervention and one week after intervention

Method of measurement

Spectrophotometer

2

Description

Alanine amino transferase

Timepoint

Before intervention, after intervention and one week after intervention

Method of measurement

Spectrophotometer

3

Description

Reactive Protein C

Timepoint

Before intervention, after intervention and one week after intervention

Method of measurement

Autoanalyser

4

Description

High density lipoprotein

Timepoint

Before intervention, after intervention and one week after intervention

Method of measurement

HDL kit

5

Description

Triglyceride

Timepoint

Before intervention, after intervention and one week after intervention

Method of measurement

kit TG

6

Description

Cholesterol

Timepoint

Before intervention, after intervention and one week after intervention

Method of measurement

Cholesterol Kit

7

Description

Low density lipoprotein

Timepoint

Before intervention, after intervention and one week after intervention

Method of measurement

Calculate with Friedewald formula

8

Description

Evaluation of electrolytes (sodium, potassium, magnesium, phosphorus)

Timepoint

Before intervention, after intervention and one week after intervention

Method of measurement

Electrolyte analyzer

9

Description

Fasting blood sugar

Timepoint

Every day for two weeks

Method of measurement

Avtanalyzer device

10

Description

Multinational defect

Timepoint

Time intervals 24, 48, 96 hours and the end of intervention

Method of measurement

Sofa questionnaire

Secondary outcomes

1

Description

Insulin received

Timepoint

Every day for two weeks

Method of measurement

questionnaire

2

Description

Infection rate

Timepoint

Followed for 28 days

Method of measurement

questionnaire

3

Description

Duration of ventilator dependence

Timepoint

Followed for 28 days

Method of measurement

questionnaire

4

Description

mortality

Timepoint

Followed for 28 days

Method of measurement

questionnaire

5

Description

Number of hospital admissions days in the intensive care unit

Timepoint

Followed for 28 days

Method of measurement

questionnaire

6

Description

Number of hospital admissions days

Timepoint

Followed for 28 days
Method of measurement
questionnaire

7

Description
Digestive complications
Timepoint
Every day for two weeks
Method of measurement
questionnaire

8

Description
Gastrointestinal intolerance
Timepoint
Every day for two weeks
Method of measurement
questionnaire

9

Description
Calorie intake
Timepoint
Every day for two weeks
Method of measurement
questionnaire

10

Description
Percentage of protein intake
Timepoint
Every day for two weeks
Method of measurement
questionnaire

Intervention groups

1

Description
Intervention group: Patients in the intervention group will receive Hypocaloric diet. After hemodynamic stabilization, enteral nutrition support will be started during the first 24-48 hours that individual will be inpatient, and will be prescribed in form of bolus every three hours (6 times in 24 hours). Subjects of hypocaloric diet group will receive 40 percent of calculated calorie by using indirect calorimetry device during the first 24-48 hours of being in patient, and this amount will be reach to100 percent of patient's need in one week. This group will be fed exactly similar to control group by full-calorie method after 7 days of intervention.

Category
Treatment - Other

2

Description

Patients of first group that defined as control group, which is the full-calorie group, will receive 80 to 100 percent of their actual energy requirement as nutrition support in form of enteral method that will be started during the first 24-48 hours of being inpatient. The required calorie will be calculated through indirect calorimetry and intervention will be continued for 7 days

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Mashhad Shahid Kamyab Hospital
Full name of responsible person
Dr. Mohammad Safarian
Street address
Shahid Kamyab Hospital, Fadaieyan Eslam Avenue,
Nakhrisi Square, Mashhad-Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191
Phone
+98 51 3859 2121
Email
SafarianM@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Farid Najafi
Street address
Vice- Chancellery of Research & Technology Affairs,
Building No. 2 of Kermanshah University of Medical
Sciences, Naft Square, Shahid Beheshti blvd
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3838 4185
Email
fnajafi@kums.ac.ir
Grant name
Grant code / Reference number
**Is the source of funding the same sponsor
organization/entity?**
Yes
Title of funding source

Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Seyyede Zeinab Mousavian
Position
MS.c student in Nutrition Sciences/chief cooperorator of plan
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
Public Health faculty, Next to the Farabi Hospital,
Dolat Ababd blvd, Isar Square, Imam Hosein Exp
City
Kermanshah
Province
Kermanshah
Postal code
6719851351
Phone
+91 83382 81991
Email
sz.mousavian@kums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Yahya Pasdar
Position
Associate Professor of Nutrition Sciences
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Public Health faculty, Next to the Farabi Hospital,

Dolat Ababd blvd, Isar Square, Imam Hosein Exp
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 1826 2005
Email
yahya.pasdar@kums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Seyyede Zeynab Mousavian
Position
MS.c student in Nutrition Sciences/ chief cooperorator of plan
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
Public Health faculty, Next to the Farabi Hospital,
Dolat Ababd blvd, Isar Square, Imam Hosein Exp
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 1826 2005
Email
sz.mousavian@kums.ac.ir

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

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available