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)

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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

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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
Avtanalizer 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

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 cooperator of plan

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

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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

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Person responsible for updating data

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Kermanshah University of Medical Sciences

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Position
MS.c student in Nutrition Sciences/ chief cooperator of plan

Latest degree
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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
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