Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jul 2026

The effects of hypo-caloric and full-caloric enteral feeding on metabolic stress indices of patients with multiple trauma, during the first week

Protocol summary

Study aim

Determination and comparison of the effects of hypo-caloric and full-caloric enteral feeding on metabolic stress indices of patients with multiple trauma, during the first week of admission in the general intensive care unit

Design

Controlled clinical trial with parallel group, single-blind, randomized,

Settings and conduct

The present study was a single-blind controlled clinical trial examining the effect of calorie intake on metabolic stress indices in patients with general trauma.Participants (80 individuals, 18 to 65 years) will be recruited from the intensive care unit of Shahid Kamyab Hospital and will be divided into two groups of hypo-calorie and full-calorie diet recipients.Patients in both groups will be provided with intestinal nutritional support during the first 24-48 hours after stabilization of the hemodynamic status and will be fed bolus at three-hour intervals.

Participants/Inclusion and exclusion criteria

Inclusion criteria:age between 18-65 Gastrointestinal tract with normal function and indications of Entral Nutrition Diagnosis of moderate to severe trauma based on GCS (4-14);Exclusion criteria: failure to start enteral nutrition during the first 48 hours of admission Patients who are less than 96 hours in intensive care unit

Intervention groups

Intervention group: Start the intestinal feeding of a patient with a hypo- calorie intake (30-40% of the daily calorie requirement) and gradually increase and reach it (70-80% of the required calorie requirement) and continue feeding at the same rate until day 14 Control group: Start the intestinal feeding of a patient with a full-calorie intake (70-80% of the daily calorie requirement) and gradually increase and reach it (90-95% of the required calorie requirement) and continue feeding at the same rate until day 14

Main outcome variables

UUN,serum Lactate,FBS,Weight,MAC,Body temperature,REE

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191124045482N1**
Registration date: **2019-12-28, 1398/10/07**
Registration timing: **prospective**

Last update: **2019-12-28, 1398/10/07**
Update count: **0**

Registration date

2019-12-28, 1398/10/07

Registrant information

Name

roya ranjbar miri

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3882 8574

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-05, 1398/10/15

Expected recruitment end date

2020-02-04, 1398/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of hypo-caloric and full-caloric enteral feeding on metabolic stress indices of patients with multiple trauma, during the first week

Public title

The effects of hypo-caloric and full-caloric enteral feeding on metabolic stress indices of patients with multiple trauma, during the first week of admission in the general intensive care unit

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age between 18-65 years Gastrointestinal tract with normal function and indications of Enteral Nutrition Diagnosis of moderate to severe trauma based on GCS (4-14) Enteral ability to feed in the first 24 to 48 hours of admission Completion of informed consent form from patients' first-degree reletives

Exclusion criteria:

failure to start enteral nutrition during the first 48 hours of admission Presence Cancer, diabetes, and cardiovascular disease pregnancy Patients who are less than 96 hours in intensive care unit

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, the permuted block randomization method with blocks of size 4 is used. According to the sample size of 80, 20 blocks of size four will be produced using the online site (www.sealedenvelope.com)

Blinding (investigator's opinion)

Single blinded

Blinding description

After conscious reporting from the patient or their companions, the patient is randomly assigned to either hypo-caloric and full-caloric enteral feeding.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Mashhad University of Medical Sciences

Street address

Department of Nutrition, Faculty of Medicine Mashhad University of Medical Sciences (MUMS) Paradise Daneshgah Azadi Square Post code 91779-48564 Mashad, Iran

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Razavi Khorasan

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Approval date

2019-02-05, 1397/11/16

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.574

Health conditions studied

1

Description of health condition studied

multiple truama

ICD-10 code

S00-T98

ICD-10 code description

Injury, poisoning and certain other consequences of external causes

Primary outcomes

1

Description

24 hours urea urine

Timepoint

at the baseline, 7 and 14 days after intervention

Method of measurement

Auto-analyzer

2

Description

Triglyceride

Timepoint

at the baseline, 7 and 14 days after intervention

Method of measurement

Auto-analyzer

3

Description

serum lactate

Timepoint

at the baseline, 7 and 14 days after intervention

Method of measurement
Auto-analyzer

4

Description
Blood Glucose
Timepoint
at the baseline, 7 and 14 days after intervention
Method of measurement
Auto-analyzer

5

Description
Body temperature
Timepoint
at the baseline, 7 and 14 days after intervention
Method of measurement
Rectal temperature measurement using mercury thermometer

6

Description
Resting energy expenditures
Timepoint
at the baseline, 7 and 14 days after intervention
Method of measurement
Indirect calorimetric device

Secondary outcomes

1

Description
Mid arm circumference
Timepoint
At the baseline and 14 days after starting intervention
Method of measurement
Measuring meters

2

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

3

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

4

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

5

Description
Number of hospital admissions days
Timepoint
Followed for 28 days
Method of measurement
questionnaire

Intervention groups

1

Description
Intervention group: Patients in the intervention group will receive Hypocaloric diet. Subjects of hypocaloric diet group will receive 40 -30 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 to70-80 percent of patient’s need in one week. Patients in the intervention group will be fed 70-80% of their required calories by the end of the intervention (day 14 of hospitalization).
Category
Treatment - Other

2

Description
Control group: Patients in the Control group will receive full-calorie diet. Subjects of full-calorie diet group will receive 70-80 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 to90-95 percent of patient’s need in one week. Patients in the Control group will be fed 90-95% of their required calories by the end of the intervention (day 14 of hospitalization).
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Kamyab Hospital
Full name of responsible person
Alireza Mahmoudi Gharaei
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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number
970840

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Roya Ranjbar Miri

Position
M.Sc. student

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

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Person responsible for updating data

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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