Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jul 2026

The effect of low Dietary Inflammatory Index formula on inflammatory and metabolic biomarkers in multiple trauma patients in Intensive Care Unit: a single blind randomized controlled trial

Protocol summary

Study aim

Determination of the Effect of Formula with Low Inflammatory index on Inflammatory and Metabolic Factors in Multiple Trauma Patients Admitted to Shahid Kamyab Hospital in Mashhad

Design

In this study, 20 adult patients aged 18-65 years old with a general trauma after admission to ICU were selected according to the inclusion criteria and matched according to age, sex, type of lesions, GCS and randomly will be inter into two groups . The sampling method is not randomly (based on the purpose and according to the inclusion criteria and exclusion criteria). The method of collecting information is in a laboratory and observational tool.

Settings and conduct

In this study, 20 adult patients aged 18-65 years old were included 24-48 hours after being admitted to the intensive care unit of Shahid Kamyab Hospital in Mashhad based on inclusion criteria and randomly divided into two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 18-65 Gastrointestinal tract with normal function and indications of Enteral 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 Any history of cardiovascular disease Patients who are less than 96 hours in intensive care unit. Patients who are predicted to die within 12 hours of admission to the intensive care unit. Patients who are contraindicated for receiving enteral nutrition Patient dissatisfaction or their legal guardian

Intervention groups

Receiving enteral formula gavage with low inflammatory index (anti-inflammation) for 2 weeks in case group and receiving standard gavage for 2 weeks in control group.

Main outcome variables

hs-CRP, TNF-α ALT, AST, ALP BG HDL-c, LDL-c, Total cholesterol, TG

General information

Reason for update

Due to the difference in the colors of the intervention and standard formulas in this study, the physician and nurses could not be blinded regarding patient allocation.

Acronym

IRCT registration information

IRCT registration number: **IRCT20180515039674N1**
Registration date: **2018-09-04, 1397/06/13**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-20, 1399/02/31**
Update count: **1**

Registration date

2018-09-04, 1397/06/13

Registrant information

Name
Mohammad Safarian
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-21, 1397/03/31

Expected recruitment end date

2018-10-22, 1397/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of low Dietary Inflammatory Index formula on inflammatory and metabolic biomarkers in multiple trauma patients in Intensive Care Unit: a single blind randomized controlled trial

Public title

The effect of anti-inflammatory formula to reduce inflammation in intensive care unit patients

Purpose

Treatment

Inclusion/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 Any history of cardiovascular disease Patients who are less than 96 hours in intensive care unit. Patients who are predicted to die within 12 hours of admission to the intensive care unit. Patients who are contraindicated for receiving enteral nutrition Patient dissatisfaction or their legal guardian

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

After selecting patients according to the inclusion criteria, they are matched according to age, sex, GCS and type of lesion, and randomly divided into one of two intervention and control groups. Patients will be randomly divided into intervention and control groups using statistical software and block randomization.

Blinding (investigator's opinion)

Double blinded

Blinding description

After preparation of sachets (containing vitamins, salts and nutrients mentioned) by pharmaceutical specialist team and professors of the Pharmaceutical group and then adding it to the standard Enteralmeal formulas for formulation of the intervention group, both the formulas include the control group and the intervention is transferred to the hospital and In the hospital's kitchen after the preparation of the gavage solution in a same bottle as shape, numbered and encoded and transferred to the ICU and provided to the nurse concerned.

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

City

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Province

Razavi Khorasan

Postal code

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Approval date

2018-05-14, 1397/02/24

Ethics committee reference number

IR.MUMS.fm.REC.1397.108

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

Tumor necrosis factor-α

Timepoint

at the baseline, 7 and 14 days after intervention

Method of measurement

Enzyme-linked immunosorbent assay

2

Description
hs-CRP
Timepoint
at the baseline, 7 and 14 days after intervention
Method of measurement
Enzyme-linked immunosorbent assay

Secondary outcomes

1

Description
Alkaline phosphatase
Timepoint
At the baseline and 14 days after starting intervention
Method of measurement
Auto-analyzer

2

Description
Aspartate Aminotransferase
Timepoint
At the baseline and 14 days after starting intervention
Method of measurement
Auto-analyzer

3

Description
Alanine Aminotransferase
Timepoint
At the baseline and 14 days after starting intervention
Method of measurement
Auto-analyzer

4

Description
Blood Glucose
Timepoint
At the baseline and 14 days after starting intervention
Method of measurement
Auto-analyzer

5

Description
Triglyceride
Timepoint
At the baseline and 14 days after starting intervention
Method of measurement
Auto-analyzer

Intervention groups

1

Description
Intervention group: To receive eternal formula (gavage) with low inflammation profile (anti-inflammation) for two weeks.
Category
Treatment - Other

2

Description
Control group: To receive standard eternal formula (gavage) for two weeks.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Kamyab Hospital
Full name of responsible person
علیرضا محمودی قرایی
Street address
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Sponsors / Funding sources

1

Sponsor
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Grant name

Grant code / Reference number
961093

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
Sajedeh Jandari
Position
M.Sc. student
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

If necessary, the data will be unidentifiable and in accordance with the ethical standards existing at the deputy of research of the Faculty of Medical Sciences of Mashhad.

When the data will become available and for how long

After finishing the study and defending of the student's dissertation, the findings of the study will be published as a thesis and valid articles.

To whom data/document is available

All researchers in the field of health have the opportunity to use the findings of this study if they have written permission from the vice chancellor for research in Mashhad University of Medical Sciences.

Under which criteria data/document could be used

After obtaining permission from the deputy of research of Mashhad University of Medical Sciences and the main executor of the project, further studies in this field will be available for the researchers.

From where data/document is obtainable

Research Vice-President of Mashhad University of Medical Sciences, principal executor of the project (Dr. Mohammad Safarian, Associate Professor of Nutrition)

What processes are involved for a request to access data/document

Obtaining a written license from the Research Vice-President of Mashhad University of Medical Sciences, then referring to Mashhad University of Medical Sciences and obtaining permission from the principal moderator and head director of the nutrition department.

Comments