

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 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- $\alpha$  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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3800 2423

###### Email address

safarianm@mums.ac.ir

##### 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 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

**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**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948564

**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 trauma

**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- $\alpha$

**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**

Fadaeyan-e-Islam 10 , Fadaeyan e Islam Street Blvd

#### **City**

Mashhad

#### **Province**

Razavi Khorasan

#### **Postal code**

9166637477

#### **Phone**

+98 51 3802 6120

#### **Fax**

#### **Email**

skh@mums.ac.ir

#### **Web page address**

<http://h-kamyab.mums.ac.ir/>

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Mashhad University of Medical Sciences

#### **Full name of responsible person**

Saeid Eslami

#### **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**

Mashhad

#### **Province**

Razavi Khorasan

#### **Postal code**

9177948564

**Phone**  
+98 51 3882 8888

**Fax**  
+98 51 3882 8560

**Email**  
med.faculty@mums.ac.ir

**Web page address**

**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

**Latest degree**  
Bachelor

**Other areas of specialty/work**  
Nutrition

**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**  
Mashhad

**Province**  
Razavi Khorasan

**Postal code**  
9177948564

**Phone**  
+98 51 3882 7034

**Email**  
Jandaris951@mums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**  
Mohammad Safarian

**Position**  
Associate professor in Clinical Nutrition

**Latest degree**  
Ph.D.

**Other areas of specialty/work**  
Nutrition

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

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Razavi Khorasan

**Postal code**  
9177948564

**Phone**  
+98 51 3800 2423

**Email**  
SafarianM@mums.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**  
Mashhad University of Medical Sciences

**Full name of responsible person**  
Sajedeh Jandari

**Position**  
M.Sc. student

**Latest degree**  
Bachelor

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Nutrition

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Department of Nutrition, Faculty of Medicine Mashhad  
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Mashad, Iran

**City**  
Mashhad

**Province**  
Razavi Khorasan

**Postal code**  
9177948564

**Phone**  
+98 51 3882 7034

**Email**  
Jandaris951@mums.ac.ir

## 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**