Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Design and development of an anti-inflammatory formula for Oral Nutrition Support (ONS) and its effects on inflammatory markers, antioxidants status and clinical outcomes in critically ill patients admitted to the intensive care unit: A double blined randomized control trial

Protocol summary

Study aim

Design and development of an anti-inflammatory formula for Oral Nutrition Support (ONS) and its effects on inflammatory markers, antioxidants status and clinical outcomes in critically ill patients admitted to the intensive care unit

Design

In this study, 74 critically ill adult patients, 24-48 hours after being admitted to the special care unit are selected based on the inclusion criteria and randomly assigned to two groups. After determining the daily needs of the intervention group and the control group, respectively, 500 cc of anti-inflammatory formula and 500 cc of standard formula will be received in 2 doses and in the form of a bolus, and the rest of the energy needed by the patients will be provided through hospital gavage.

Settings and conduct

This study is conducted on critically ill patients admitted to the intensive care unit of Imam Reza (AS) Mashhad Hospital. In this study, 74 critically ill patients were randomly assigned to one of two intervention or control groups and were subjected to intervention with anti-inflammatory formulation or standard formulation for 14 days. In this study, the patients and the statistical analyzer were blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria o Age 18-65 years o Digestive system with normal function o Has criteria for enteral nutrition Non-entry criteria o Patients who are hospitalized in the intensive care unit for less than 96 hours. o Patients who have a history of underlying diseases such as diabetes, congenital and immune disorders, kidney and liver failure, and pancreatitis. o Lack of consent of the patient or his legal guardian

Intervention groups

Intervention group: 500 cc of anti-inflammatory oral nutrition formula Control group: 500 cc Standard Formula (Standard Entrameal)

Main outcome variables

Inflammatory factors hs-CRP and ESR TAC and MDA antioxidant factors SOFA disease severity measure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210217050393N4**
Registration date: **2023-08-05, 1402/05/14**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-05, 1402/05/14**
Update count: **0**

Registration date

2023-08-05, 1402/05/14

Registrant information

Name

REZA REZVANI

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3800 2418

Email address

rezvanir@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-15, 1402/04/24

Expected recruitment end date
2024-08-21, 1403/05/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Design and development of an anti-inflammatory formula for Oral Nutrition Support (ONS) and its effects on inflammatory markers, antioxidants status and clinical outcomes in critically ill patients admitted to the intensive care unit: A double blined randomized control trial

Public title
Effect of an anti-inflammatory formula for Oral Nutrition Support (ONS) in critically ill patients admitted to the intensive care unit
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 65-18 years Normal Gastrointestinal function Having indication for enteral nutrition
Exclusion criteria:
Impossibility of enteral feeding in the first 48 hours of admission History of underlying advanced heart disease Patients who are hospitalized in the intensive care unit for less than 96 hours. Patients expected to die within 12 hours of admission to the intensive care unit. Patients who do not have an indication for enteral nutrition on the first day, and based on the diagnosis of the intensive care unit, it is confirmed and predicted that they will not be able to receive enteral nutrition in the future. Patients who are under nutritional support by complete Parenteral Nutrition. Patients who have a history of underlying disease such as uncontrolled diabetes, congenital and immune disorders, advanced kidney and liver failure, and pancreatitis. Lack of consent of the patients or their legal guardian
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **74**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization will be with blocks of 4, the random list will be created by https://www.sealedenvelope.com/. Patients are assigned to two control and intervention groups using sealed envelopes with block randomization method. In this way, in blocks of 4 which are divided into four states and each of these states is randomly selected from the sealed envelopes, 4 people in the control and intervention groups are allocated based on the selected state of the sealed envelope. It will be given. The same process continues until the allocation of all participants in the control and intervention groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
After the preparation of the sachet (containing the vitamins, minerals and nutrients mentioned) by the specialized pharmacy team and the professors of the pharmaceuticals department and then adding it to the standard Intramil formula to prepare the formula of the intervention group, both the control and intervention group formulas are transferred to the hospital and In the hospital kitchen, after preparing the gavage solution in bottles of the same shape, it is numbered and coded, and it is transferred to the ICU and given to the relevant nurse, and to the patients who were previously divided into two control and intervention groups. The approval will be divided according to the amount of calories required and the amount of volume requested by the patient's doctor. Considering that the researchers, nurses and patients do not know about the numbering and coding of the gavage solution of the patients, and due to the identical appearance, texture and organoleptic characteristics of the gavage solutions of the two groups, the blinding process is done with great care.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
research ethic committees of School of Medicine - Mashhad University of Medical Sciences
Street address
Azadi Square, Campus of University, Mashhad, Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Approval date
2023-05-30, 1402/03/09
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1402.112

Health conditions studied

1

Description of health condition studied
sepsis
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Acute respiratory distress syndrome (ARDS)
ICD-10 code
ICD-10 code description

3

Description of health condition studied
critically ill patients
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
(hs-crp) Inflammatory factor
Timepoint
At baseline, day 7 and day 14
Method of measurement
ELISA kit

2

Description
ESR inflammatory factor
Timepoint
At baseline, day 7 and day 14
Method of measurement
ELISA kit

3

Description
TAC antioxidant factor
Timepoint
At baseline, day 7 and day 14
Method of measurement
ELISA kit

4

Description
MDA antioxidant factor
Timepoint
At baseline, day 7 and day 14
Method of measurement
ELISA kit

5

Description
SOFA disease severity measure
Timepoint
At baseline, day 7 and day 14
Method of measurement
SOFA score questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: after determining the daily needs of the intervention group, 500 cc of the anti-inflammatory oral nutritional supplement (ONS) formula in 2 meals and in the form of a bolus, and the rest of the energy needed by the patient is also provided through hospital gavage.
Category
Treatment - Other

2

Description
Control group: After determining the daily needs of the control group, 500 cc of the standard formula (Standard Entrameal) in 2 meals and in the form of a bolus and the rest of the energy required by the patient is also provided through hospital gavage.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Intensive Care Units of ImamReza Hospital
Full name of responsible person
Reza Rezvani
Street address
Imam Reza hospital-Imam Reza Square, Ibn-e Sina Avenue, Mashhad - Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Reza Rezvani
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مشهد، میدان آزادی، دانشگاه فردوسی، دانشکده پزشکی، دپارتمان تغذیه
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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
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
PhD student
Latest degree
Master
Other areas of specialty/work
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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
Yes - There is 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
Yes - There is 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

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. Reza Rezvani)

What processes are involved for a request to access data/document
Obtaining written permission from the Research Vice-Chancellor of Mashhad University of Medical Sciences, then referring to the Faculty of Medicine of Mashhad University of Medical Sciences and obtaining permission from the main project manager (Dr. Reza Rezvani) and the second supervisor (Dr. Majid Ghayour-Mobarhan) and the director of the Department of Nutrition

Comments