

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Effects of early versus delayed enteral nutrition and closed versus open enteral nutrition on high-sensitivity C-Reactive Protein and Tumor Necrosis Factor Alpha in 24 patients admitted in surgery Intensive Care Units

Protocol summary

Summary

The objective of this randomized single-blind study is to essay affects of early versus delayed enteral nutrition feeding as well as closed versus open enteral nutrition formula on serum high-sensitivity C-Reactive Protein and Serum Tumor Necrosis Factor Alpha among patients admitted in surgery intensive care unit. Effects of each groups of intervention will be essayed on Simplified Acute Physiology Score (SAPS II) and Sequential Organ Failure Assessment Score (SOFA), too. Patients will be divided into four groups, randomly, after filling constant forms. Half of subject will receive early enteral feeding and the rest will nourished by delayed enteral feeding. Each group will be divided into two sub-groups: subject will be fed by closed formula and those subjects that will be fed by open formula. Duration of the study is 7 days. Subjects will be included if their Acute Physiology and Chronic Health Evaluation (APACHE) score will be between 15 to 25 and be stayed in intensive care units for at least 72 hours. Patients will be excluded if aged less than 18 years or have hepatic or nephritic syndromes. Total number of subjects will be 24. Primary outcome is to essay affects of early versus delayed enteral nutrition feeding and closed versus open enteral nutrition formula on serum high-sensitivity C-Reactive Protein and serum Tumor Necrosis Factor Alpha.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201403042017N19**
Registration date: **2014-04-13, 1393/01/24**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-04-13, 1393/01/24

Registrant information

Name

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Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2014-05-05, 1393/02/15

Expected recruitment end date

2014-10-07, 1393/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of early versus delayed enteral nutrition and closed versus open enteral nutrition on high-sensitivity C-Reactive Protein and Tumor Necrosis Factor Alpha in 24 patients admitted in surgery Intensive Care Units

Public title

Effects of early versus delayed enteral nutrition and closed versus open enteral nutrition on high-sensitivity C-Reactive Protein and Tumor Necrosis Factor Alpha in 24 patients admitted in surgery Intensive Care Units

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: aged more than 18 years; those who might be stayed in Intensive Care Units for more than 72 hours; Patients with Acute Physiology and Chronic Health Evaluation more than 15-25. Exclusion criteria: aged less than 18 years; patients with hepatic disorders; patients with nephritic syndrome; Hemodynamically unstable; increased lactate in serum; Pregnant women.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz university of Medical Sciences

Street address

Golgasht St.

City

Tabriz

Postal code

Approval date

2014-02-23, 1392/12/04

Ethics committee reference number

92205

Health conditions studied

1

Description of health condition studied

Unspecified protein-energy malnutrition

ICD-10 code

E46

ICD-10 code description

Protein-energy imbalance NOS

Primary outcomes

1

Description

Serum high-sensitivity C-Reactive Protein

Timepoint

In first, third, fifth and seventh days

Method of measurement

Blood sampling

2

Description

Serum Tumor Necrosis Factor Alpha

Timepoint

In following days: first, third, fifth and seventh.

Method of measurement

Blood sampling

Secondary outcomes

1

Description

Simplified Acute Physiology Score (SAPS II)

Timepoint

In following days: first, third, fifth and seventh .

Method of measurement

By measuring following parameters: Type of admission, , Chronic diseases, Glasgow , , Syst. Blood Pressur, , If MV or CPAP , PaO2/FiO2(mmHg), , Urine output, , WBC,, Potassium,, Sodium,, HCO3,, Bilirubin,, Serum Urea or , BUN, , Heart rate,, Temperature

2

Description

Sequential Organ Failure Assessment Score (SOFA)

Timepoint

In following days: first, third, fifth and seventh

Method of measurement

PaO2/FiO2 (mmHg), Glasgow coma scale, Mean Arterial Pressure, Bilirubin (mg/dl) , Platelets×103/μl, Creatinine (mg/dl)

Intervention groups

1

Description

Enteral feeding by open and closed formula in delayed and early feeding groups over 7 days

Category

Rehabilitation

Recruitment centers1**Recruitment center****Name of recruitment center**

Emam Reza Hospital

Full name of responsible person**Street address****City**

Tabriz

2**Recruitment center****Name of recruitment center**

Golsetan Hospital

Full name of responsible person**Street address****City**

Ahvaz

3**Recruitment center****Name of recruitment center**

Shohada Hospital

Full name of responsible person**Street address****City**

Tabriz

4**Recruitment center****Name of recruitment center**

Şahriar Hospital

Full name of responsible person**Street address****City**

Tabriz

5**Recruitment center****Name of recruitment center**

Razi Hospital

Full name of responsible person**Street address****City**

Ahvaz

Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr Alireza Ostadrahimi

Street addressNutrition Faculty, Attare Neishabouri Avenue,
Golgasht street,**City**

Tabriz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

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PhD in Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty