

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Effect of enteral feeding composition on inflammatory mediators, oxidative stress and outcomes in Intensive Care Unit patients with acute respiratory failure

Protocol summary

Summary

This study aimed to investigate the effect of enteral feeding's macronutrient composition on inflammatory mediators, oxidative stress and outcomes in Intensive Care Unit (ICU) patients with acute respiratory failure. In this double-blind randomized control trial, 42 patients of both sexes and diagnosed with acute respiratory failure in ICU that receive enteral feeding, will be randomly assigned to three groups of 14 each. First Intervention group; high-protein low-carbohydrate diet with high olive oil, the second intervention group; high-protein low-carbohydrate diet with high sunflower oil and control; high-protein kitchen formula. Intravenous levels of uric acid, hs-CRP, IL-6 and TAC measured at days 0 and 10. As well as, organ failure, duration of ventilation, length of ICU stay and mortality rates will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015021614901N6**

Registration date: **2015-03-27, 1394/01/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-03-27, 1394/01/07

Registrant information

Name

Zahra Vahdat Shariatpanahi

Name of organization / entity

Faculty of Nutrition and Food Sciences, Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2235 7484

Email address

z.shariatpanahi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

National Nutrition and Food Technology Research Institute

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2015-07-23, 1394/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of enteral feeding composition on inflammatory mediators, oxidative stress and outcomes in Intensive Care Unit patients with acute respiratory failure

Public title

Feeding composition and acute respiratory failure

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: enrolled in ICU; age older than 18 years old; need to be mechanically ventilation; have enteral feeding; no previous diabetes, HIV infection, nervous system, liver failure, nephrotic syndrome; not passed more than 48 hours from diagnose of acute respiratory failure Exclusion criteria: death at less than three days of enteral feeding administration; extubation at less than

three days of enteral feeding administration

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Nutrition and Food Technology Research Institute, Faculty of Nutrition and Food Sciences,

Street address

3, Baran, West Arghavan, Farahzadi Blvd., Shahrak Qods

City

Tehran

Postal code

Approval date

2015-01-13, 1393/10/23

Ethics committee reference number

054575

Health conditions studied

1

Description of health condition studied

Acute Respiratory Failure

ICD-10 code

J96.0

ICD-10 code description

Acute Respiratory Failure

Primary outcomes

1

Description

length of ventilation

Timepoint

daily

Method of measurement

observation

Secondary outcomes

1

Description

hs-CRP

Timepoint

day 0, day 10

Method of measurement

ELIZA

2

Description

TAC

Timepoint

day 0, day 10

Method of measurement

autoanalyzer

3

Description

uric acid

Timepoint

day 0, day 10

Method of measurement

ELIZA

4

Description

length of ICU stay

Timepoint

daily

Method of measurement

observation

5

Description

organ failure

Timepoint

daily

Method of measurement

clinical and paraclinical

6

Description

mortality

Timepoint

daily

Method of measurement

observation

Intervention groups

1

Description

Intervention 1: high-protein low carbohydrate diet with high olive oil

Category

Other

2

Description

Intervention 2: high-protein low carbohydrate diet with high sunflower oil

Category

Other

3

Description

Control: common high protein kitchen diet

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasul Akram Hospital

Full name of responsible person

Dr Nader Tavakoli

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

National Nutrition and Food Technology Research Institute

Full name of responsible person

Dr Majid Hajifaraji

Street address

3, Baran, West Arghavan, Farahzadi Blvd., Shahrak Qods.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

National Nutrition and Food Technology Research

Institute

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

Faculty of Nutrition and Food Sciences, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zahra Vahdat Shariatpanahi

Position

MD, PhD in nutrition

Other areas of specialty/work

Street address

3, Baran, West Arghavan, Farahzadi Blvd., Shahrak Qods,

City

Tehran

Postal code

Phone

+98 21 2235 7483

Fax

Email

nutritiondata@yahoo.com,
z.shariatpanahi@sbmu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of Nutrition and Food Sciences, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zahra Vahdat Shariatpanahi

Position

MD, PhD in nutrition

Other areas of specialty/work

Street address

3, Baran, West Arghavan, Farahzadi Blvd., Shahrak Qods, Tehran, I.R. Iran

City

Tehran

Postal code

Phone

+98 21 2235 7483

Fax

Email

nutritiondata@yahoo.com,
z.shariatpanahi@sbmu.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Faculty of Nutrition and Food Sciences, Shahid
Beheshti University of Medical Sciences

Full name of responsible person

Zahra Vahdat Shariatpanahi

Position

MD, PhD in nutrition

Other areas of specialty/work

Street address

3, Baran, West Arghavan, Farahzadi Blvd., Shahrak
Qods, Tehran, I.R. Iran

City

Tehran

Postal code

Phone

+98 21 2235 7483

Fax

Email

nutritiondata@yahoo.com,
z.shariatpanahi@sbmu.ac.ir

Web page address

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