

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Effect of macronutrient composition of the enteral diet on glycemic control in critically ill patients

Protocol summary

Summary

The aim of this study is to evaluate the preventive effects of high fat enteral feeding on glycemic control and clinical outcomes in critically ill patients. 48 normoglycemic patients, admitted to intensive care unit will randomly classified into three groups of 14 each. Control group (A) will receive carbohydrate-based diet (protein:20%, fat:30%, carbohydrate:50%), study groups will receive two types of high fat diet; group B (protein:20%, fat:45% including half of olive oil and half sunflower oil, carbohydrate:35%) and group C (protein:20%, fat:45% including sunflower oil, carbohydrate:35 %) in the first 48 h of admission. Plasma and capillary glucose levels, insulin requirements, Serum HLA-cholesterol level, organ failure and mortality will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016111914901N9**

Registration date: **2016-11-27, 1395/09/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-11-27, 1395/09/07

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

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Recruitment status

Recruitment complete

Funding source

National Nutrition and Food Technology Research Institute

Expected recruitment start date

2013-08-01, 1392/05/10

Expected recruitment end date

2015-12-10, 1394/09/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of macronutrient composition of the enteral diet on glycemic control in critically ill patients

Public title

The macronutrient composition of the diet and glycemic control in ICU

Purpose

Supportive

Inclusion/Exclusion criteria

Adult patients in both sexes who will be hospitalized in ICU and initiating enteral nutrition within 48 hours following the hospital admission, will be included in this study. Patients enrolled in other studies that are pregnant or with previous diabetes, hyperglycemia on admission, Body Mass Index (BMI) \geq 30 kg/m², hyperlipidemia, liver failure, nephrotic syndrome and any contraindication to enteral nutrition, will be excluded. Patients who are discharge or die before the fifth day of enteral nutrition administration will be also excluded

from the study.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **48**

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**

critically ill patients

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The glycemic control

Timepoint

daily

Method of measurement

glucose oxidas

2**Description**

Lipid profile

Timepoint

day 0 and 10

Method of measurement

ELIZA

Secondary outcomes**1****Description**

organ failure

Timepoint

daily

Method of measurement

clinical and paraclinical

2**Description**

length of ICU stay

Timepoint

daily

Method of measurement

observation

Intervention groups**1****Description**

intervention 1:high protein carbohydrate based diet

Category

Other

2**Description**

intervention 2:high protein fat based based diet with
high olive oil

Category

Other

3**Description**

intervention 3:high protein fat based based diet with
high sunflower oil

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasul Akram Hospital

Full name of responsible person

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

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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