

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of fat based versus glucose based enteral nutrition on serum glucose levels and clinical outcomes in hyperglycemic patients in ICU

Protocol summary

Summary

This randomized double blind clinical trial will be conducted for detecting the Influence of fat based versus glucose based enteral nutrition on serum glucose levels and clinical outcomes in hyperglycemic patients in ICU. 80 patients with age range in 18-65 years old, random blood sugar at 200mg/dl or above, with enteral feeding started in the first 24-48 hours after hospitalization and continued at least for 5 days, patients with lack of liver and kidney failure, nephrotic syndrome, hyperlipidemia, sepsis, infection and bed sores, no obesity; no history of taking part in other studies during the last 30 days will be included. Patients with taking glucose elevating agents (such as glucocorticoids and some cardiac agents...), expiration or discharge in 5 days after receiving first feeding will be excluded. Subjects will be divided into two groups. Control group will receive handmade enteral nutrition formula with macronutrient composition as protein; 20%; CHO; 50%; fat; 30% from total provided calorie. Intervention group will receive a formula with protein; 20%; CHO; 35%; fat; 45% from total provided calorie. Patients will receive formula through of NGT or PEG maximally for 15 consecutive days or until the end of ICU hospitalization.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015100414901N7**

Registration date: **2015-11-04, 1394/08/13**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-11-04, 1394/08/13

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)

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Recruitment status

Recruitment complete

Funding source

Emam Khomeini Treatment and Educational Center

Expected recruitment start date

2015-11-11, 1394/08/20

Expected recruitment end date

2016-06-09, 1395/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of fat based versus glucose based enteral nutrition on serum glucose levels and clinical outcomes in hyperglycemic patients in ICU

Public title

Fat based enteral nutrition for glucose control in ICU

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Hospitalization in intensive care unit; Being over 18 and under 65 years old; Nasogastric or PEG enteral feeding Started in the first 24-48 hours after

hospitalization and continued at least for 5 days; Random blood sugar at 200mg/dl or above; Lack of liver and kidney failure; Lack of Nephrotic syndrome; Lack of hyperlipidemia; Lack of sepsis , infection and bed sores; Lack of obesity; No history of taking part in other studies during the last 30 days; Exclusion criteria: Expiration or discharge in 5 days after receiving first feeding; No taking glucose elevating agents(such as glucocorticoids and some Cardiac agents,...)

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

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

1

Registry name

Clinicaltrials.gov

Secondary trial Id

Nct02584907

Registration date

2015-10-01, 1394/07/09

Ethics committees

1

Ethics committee

Name of ethics committee

International Branch of Shahid Beheshti University of Medical Sciences

Street address

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

City

Tehran

Postal code

Approval date

2015-09-22, 1394/06/31

Ethics committee reference number

34199/1394/

2

Ethics committee

Name of ethics committee

Urmia medical sciences university

Street address

Research and technology vice chancellor- djahad Ave- Resalat Bld-Urmia,iran

City

Urmia

Postal code

5714783734

Approval date

2015-10-28, 1394/08/06

Ethics committee reference number

IR.UMSU.REC.1394.261

Health conditions studied

1

Description of health condition studied

Hyperglycemia

ICD-10 code

R73.9

ICD-10 code description

Hyperglycaemia, unspecified

Primary outcomes

1

Description

Mean random Blood Sugar

Timepoint

Daily

Method of measurement

mg/dl with laboratory kit

Secondary outcomes

1

Description

Ventilator dependance time

Timepoint

Daily

Method of measurement

Counting the number of days with Ventilator dependance

2

Description

ICU stay duration

Timepoint

At the end of study

Method of measurement

Counting the number of days for ICU stay

3

Description

Infection
Timepoint
Daily
Method of measurement
Incidence or Lack of incidence based on laboratory results

4
Description
Bed sore
Timepoint
Daily
Method of measurement
Incidence or Lack of incidence with viewing

5
Description
Blood Lipid Profiles
Timepoint
Weekly
Method of measurement
Mg/dl with laboratory kit

Intervention groups

1
Description
Fat based EN with predefined specific fat percent
Category
Treatment - Other

2
Description
Carbohydrate based EN with predefined specific CHO percent
Category
Treatment - Other

Recruitment centers

1
Recruitment center
Name of recruitment center
Emam Khomeini Treatment and Educational Center
Full name of responsible person
Davoud Vahabzadeh
Street address
Ershad Aven, Moddares Bld, Urmia
City
Urmia

Sponsors / Funding sources

1
Sponsor
Name of organization / entity

Emam Khomeini Treatment and Educational Center
Full name of responsible person
Davoud vahabzadeh
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Ershad Aven,Moddares Bld, Urmia
City
Urmia
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Emam Khomeini Treatment and Educational Center
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
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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