

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparison between total parenteral nutrition (TPN) Vs. partial parenteral nutrition (PPN) on serum lipids among chronic ventilator dependent patients, A multi center study

Protocol summary

Summary

The goal of this study is evaluation of two nutrition methods in chronic ventilator support patients in ICU. (TPN and PPN) Other goals includes: comparison of serum total protein Comparison of serum albumin Comparison of serum transferrin Comparison of serum total lymphocyte count Design is a prospective randomized double blind controlled clinical trial as a multi-center study. 97 patients enter the study and divide in to two groups according the inclusion criteria. Serum total protein, serum albumin, serum transferring and total lymphocyte count are measured at days 7 and 14. Inclusion criteria: chronically need to ventilatory support more than 10 days and ages between 40 to 70 and respiratory disease Exclusion: Weaning before one week TPN (Total Parenteral Nutrition): begin from central vein after all inclusion criteria. PPN (Partial Parenteral Nutrition): begin after calculating total energy needs for each patients by dividing total calorie intake equally between enteral and parenteral nutrition and if gastric secretion are less than 100 ml during 2 hours and bowel sounds are heard.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201505247457N14**
Registration date: **2015-12-24, 1394/10/03**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-12-24, 1394/10/03

Registrant information

Name

Shabnam Golshan

Name of organization / entity

Urology and Nephrology Research Center (UNRC)

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Shahid Beheshti
University of Medical Sciences

Expected recruitment start date

2012-12-31, 1391/10/11

Expected recruitment end date

2014-12-31, 1393/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between total parenteral nutrition (TPN) Vs. partial parenteral nutrition (PPN) on serum lipids among chronic ventilator dependent patients, A multi center study

Public title

comparing two methods of nutrition in ICU patients

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion: chronic ventilator supported patients in ICU

more than 10 days Age: 40 to 70 Respiratory disease
exclusion: ventilator supported patients that wean before
one week

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **97**

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

Ethics Committee of Shaheed Beheshti University of
Medical science

Street address

7th Floor , 2nd SBUMS Bldg. ,Next to Ayatollah
Taleghani Hospital, Evin , Tehran, Iran.

City

Tehran

Postal code

Approval date

2012-09-22, 1391/07/01

Ethics committee reference number

1746/الف/م

Health conditions studied

1

Description of health condition studied

chronic patient under mechanical ventilation

ICD-10 code

E64

ICD-10 code description

Sequelae of malnutrition and other nutritional
deficiencies

Primary outcomes

1

Description

lipid

Timepoint

0-1 week- 2 week

Method of measurement

serum level

Secondary outcomes

1

Description

albumin- lymphocyte- proteen serum- transferrin serum

Timepoint

0-1 week- 2 week

Method of measurement

Serum Level

Intervention groups

1

Description

Intervention group ventilatory support patients with
partial parenteral nutrition

Category

Treatment - Drugs

2

Description

control group ventilatory support patients with total
parenteral nutrition

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Labbafinejad Hospital

Full name of responsible person

Mahtab Poor Zamany Nejat Kermany

Street address

Labbafinejad Hospital, Ave Boostan 9, Ave Pasdaran

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Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice- Chancellor in Research Affairs Shahid Beheshti

University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

7th Floor , 2nd SBUMS Bldg. ,Next to Ayatollah Taleghani Hospital, Evin , Tehran, Iran.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice- Chancellor in Research Affairs Shahid Beheshti 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

Labbafinejad Hospital

Full name of responsible person

Mahtab Poor Zamany Nejat Kermany

Position

Associate Professor of Anesthesia & Intensive Care, Shaheed Beheshti University of Medical Sciences

Other areas of specialty/work

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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