

# 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

+98 21 2256 7222

##### Email address

shgolshan@unrc.ir

##### 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

##### City

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**

**Street address**

Labbafinejad Hospital, Ave Boostan 9, Ave Pasdaran

**City**

Tehran

**Postal code**

**Phone**

+98 21 2254 9029

**Fax**

+98 21 2254 9029

**Email**

drmpoorzamani@sbm.ac.ir  
drpoorzamani@yahoo.com

**Web page address**

## Person responsible for scientific 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**

**Street address**

Labbafinejad Hospital, Ave Boostan 9, Ave Pasdaran

**City**

Tehran

**Postal code**

**Phone**

+98 21 2254 9029

**Fax**

+98 21 2254 9029

**Email**

drmpoorzamani@sbm.ac.ir  
drpoorzamani@yahoo.com

**Web page address**

## Person responsible for updating data

**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**

**Street address**

Labbafinejad Hospital, Ave Boostan 9, Ave Pasdaran

**City**

Tehran

**Postal code**

**Phone**

+98 21 2254 9029

**Fax**

+98 21 2254 9029

**Email**

drmpoorzamani@sbm.ac.ir  
drpoorzamani@yahoo.com

**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*