

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Conversion of continuous infusion of regular insulin to subcutaneous glargine insulin for regulating blood glucose in patients receiving TPN: A method development study.

#### Protocol summary

##### Summary

The main objective of this study is transitioning from regular insulin provided in the parenteral nutrition (PN) mixtures to subcutaneously administered insulin glargine in patients receiving PN. This study will be conducted under controlled conditions of a randomized clinical trial. Inclusion criteria: aged over 18 years; patients who are NPO for at least 7 days or more. Exclusion criteria: autoimmune diseases, HIV infection and sepsis; diabetes mellitus; pregnancy; on dialysis or GFR < 10 mL/min (due to the pharmacokinetics of insulin); any hypersensitivity to PN components or insulin glargine; receiving corticosteroids, catecholamines, or getting PO. The study population is 28 people. During the first phase of this study, glycemic control is done in a 24-hour infusion of regular insulin in dextrose solution. After completing the first phase patients are randomly allocated in a 1:1 ratio by permuted-block randomization method to either be converted to subcutaneously administered insulin glargine pen or kept on insulin regular in dextrose solution and continued for 3 more days. In the glargine group, glycemic control is performed with once daily subcutaneous injection of insulin glargine and there is no insulin regular in dextrose solution. If needed, insulin dose adjustment is performed based on the protocol toward placing in the target range of 110 to 180 mg/dL. Values of blood glucose before PN and the end of the study are recorded.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013072314121N1**  
Registration date: **2013-08-09, 1392/05/18**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-08-09, 1392/05/18

##### Registrant information

###### Name

Mohammad Bagher Oghazian

###### Name of organization / entity

North Khorasan University of Medical Sciences  
(NKUMS)

###### Country

Iran (Islamic Republic of)

###### Phone

+98 58 3151 4000

###### Email address

oghazian@razi.tums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Tehran University of Medical Sciences (TUMS)

##### Expected recruitment start date

2012-12-01, 1391/09/11

##### Expected recruitment end date

2013-12-01, 1392/09/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Conversion of continuous infusion of regular insulin to subcutaneous glargine insulin for regulating blood glucose in patients receiving TPN: A method development study.

**Public title**

Application of a long acting insulin (glargine) in total parenteral nutrition

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: with the consent of the patient or the qualified relatives; aged over 18 years; patients who are NPO for at least 7 days or more candidates for receiving PN. Exclusion criteria: autoimmune diseases, HIV infection and sepsis; diabetes mellitus; pregnancy; on dialysis or GFR < 10 mL/min (due to the pharmacokinetics of insulin); any hypersensitivity to PN components or insulin glargine; receiving corticosteroids, catecholamines, or getting PO.

**Age**

From **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **28**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**Other design features**

This Randomized Clinical Trial study is performed on hospitalized patients who are candidates for receiving PN.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Tehran University of Medical Sciences, Deputy of Research

**Street address**

Keshavarz Blvd., Tehran University of Medical sciences, Central organization, 6th Floor

**City**

Tehran

**Postal code****Approval date**

2013-06-03, 1392/03/13

**Ethics committee reference number**

91-04-33-19864

**Health conditions studied****1****Description of health condition studied**

Total Parenteral Nutrition

**ICD-10 code**

E89.8, E46

**ICD-10 code description**

Endocrine, nutritional and metabolic diseases

**Primary outcomes****1****Description**

Glycemic control

**Timepoint**

At baseline then four times a day until the end of the study

**Method of measurement**

Blood glucose test

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

Serum electrolytes

**Timepoint**

At baseline then daily

**Method of measurement**

Measurement of electrolytes

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

Intervention 1: A 24-hour infusion of regular insulin in dextrose solution; regular insulin dose is proportional to receiving dextrose and blood glucose level.

**Category**

Treatment - Drugs

**2****Description**

Intervention 2: Insulin glargine once daily by subcutaneous injection; insulin glargine dose is proportional to receiving dextrose and blood glucose level.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center**

**Name of recruitment center**

Dr. Shariati Hospital affiliated to Tehran University of  
Medical Sciences

**Full name of responsible person**

Dr. Alireza Hayatshahi

**Street address**

**City**

Tehran

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Deputy of Research, Tehran University of Medical  
Sciences

**Full name of responsible person**

Fatemeh Saeedi

**Street address**

Enghelab Ave, Tehran University of Medical Sciences

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Deputy of Research, Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammad Bagher Oghazian

**Position**

PharmD, resident of Clinical Pharmacy

**Other areas of specialty/work**

**Street address**

Department of Clinical Pharmacy (Pharmacotherapy),  
Faculty of Pharmacy, Tehran University of Medical  
Sciences

**City**

Tehran

**Postal code**

**Phone**

+98 21 6695 4709

**Fax**

**Email**

oghazian@razi.tums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Alireza Hayatshahi

**Position**

PharmD, BCPS, Assistant Professor

**Other areas of specialty/work**

**Street address**

Department of Clinical Pharmacy (Pharmacotherapy),  
Faculty of Pharmacy, Tehran University of Medical  
Sciences

**City**

Tehran

**Postal code**

**Phone**

+98 21 6695 4709

**Fax**

**Email**

alireza.hayatshahi@gmail.com

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammad Bagher Oghazian

**Position**

PharmD, resident of Clinical Pharmacy

**Other areas of specialty/work**

**Street address**

**City**

Tehran

**Postal code**

**Phone**

+98 21 6695 4709

**Fax**

**Email**

oghazian@razi.tums.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*