

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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