Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 ml/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 untill 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 affliated 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