

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Effect of glargine Insulin on glycemia control in critically ill patients admitted to intensive care unit

Protocol summary

Summary

The aim of this study is to determine the effects of glargine insulin on glycemic control in critically ill patients admitted to intensive care unit. Eighty patients admitted to intensive care unit (Shohada Hospital - Imam Reza Hospital) will be enrolled in this study. Patients will be randomly divided into two groups. All patients who are treated with insulin and do not have sensitivity to insulin will be enrolled in the study. The control group will receive routine treatment for glycemic control that is regular insulin infusion. Intervention group will receive 10 units of glargine insulin in addition to the routine treatment. In this study, insulin will be administered in blood glucose more than 140 mg/dl. In septic patients, due to the risk of hypoglycemia, insulin will be administered in blood glucose more than 150 mg/dl. Blood glucose of the patients will be checked every hour and if 3 consecutive samples are in the target range, blood glucose measurements will be every 4 hours. For all patients, mean blood glucose level, mean daily consumption of regular insulin and hypoglycemia will be recorded. The primary outcome variable is blood glucose level and the secondary outcome variable is mortality.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201608182582N14**

Registration date: **2016-11-07, 1395/08/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-11-07, 1395/08/17

Registrant information

Name

Ata Mahmoodpoor

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 914 116 0888

Email address

mahmoodpoora@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-10-22, 1396/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of glargine Insulin on glycemia control in critically ill patients admitted to intensive care unit

Public title

Effect of long-term Insulin on glycemia control in critically ill patients admitted to intensive care unit

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All admitted diabetic patients in ICU

Exclusion: age under 18 y/o; sensitivity to insulin

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **80****Randomization (investigator's opinion)**

Randomized

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

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Random number table

Secondary Ids

empty

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

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht street

City

Tabriz

Postal code**Approval date**

2016-05-23, 1395/03/03

Ethics committee reference number

IR.TBZMED.REC.1395.159

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

Diabetes

ICD-10 code

E10

ICD-10 code description

Insulin-dependent diabetes mellitus

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

Blood Glucose

Timepoint

every one hours

Method of measurement

Laboratory

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

Mortality

Timepoint

Daily

Method of measurement

counting

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

intervention group: patients will receive 10 IU Glargine daily in addition to regular insulin therapy, subcutaneously.

Category

Treatment - Drugs

2**Description**

control group: All patients will receive routine regular insulin therapy which is Regular insulin infusion. The regular insulin (Actrapid HM, NOVO Nordisk, Denmark) will be infused via central vein catheter using a 50-ml syringe and infusion pump (Perfussor-FM pump, B Braun).

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

General ICU of Emam Reza Hospital

Full name of responsible person

Ata Mahmoodpoor

Street address

General ICU, Emam Reza Hospital

City

Tabriz

2**Recruitment center****Name of recruitment center**

ICU of Shohada Hospital

Full name of responsible person

Ata Mahmoodpoor

Street address

ICU, Shohada Hospital

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Tabriz University of Medical Sciences

Full name of responsible person

Afshin Ghalehgholab Behbahani

Street address

Tabriz University of Medical Sciences- Golgasht street

City

Tabriz

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice Chancellor for Research of Tabriz 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

Tabriz University of Medical sciences

Full name of responsible person

Abdolreza Naghizadeh

Position

Resident of Anaesthesiology

Other areas of specialty/work
Street address

Faculty of Medicine, Daneshgah street

City

Tabriz

Postal code
Phone

+98 41 3333 8413

Fax
Email

abdolreza_naghizadeh@yahoo.com

Web page address

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Ata Mahmoodpoor

Position

associate professor

Other areas of specialty/work
Street address

Faculty of Medicine, Daneshgah street

City

Tabriz

Postal code
Phone

+98 41 3334 1994

Fax
Email

mahmoodpoora@Tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Abdolreza Naghizadeh

Position

Resident of Anaesthesiology

Other areas of specialty/work
Street address

Faculty of Medicine, Daneshgah street

City

Tabriz

Postal code

5167747899

Phone

+98 41 3333 8413

Fax
Email

abdolreza_naghizadeh@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