

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

A clinical trial to compare the effectiveness of glargine insulin and regular insulin in hyperglycemic control among type II diabetic patients undergoing off-pump coronary artery bypass graft surgery

Protocol summary

Study aim

The effectiveness of glargine insulin and regular insulin in hyperglycemic control among type II diabetic patients undergoing off-pump coronary artery bypass graft surgery

Design

Totally, 80 type II diabetic candidates for surgery were chosen from the Ghaem Hospital, Mashhad, Iran. In this single-blind, controlled clinical trial, the patients are assigned into parallel groups using simple and successive sampling methods.

Settings and conduct

Type II diabetic patients who are candidates for surgery at the Ghaem Hospital, Mashhad, Iran, are chosen. In this single-blind study, sealed opaque envelopes will be used to conceal the sequencing. The person responsible for data collection is blind to group allocation and the type of drugs.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 35-75 years; sustaining ASA II; blood sugar of 150-300 mg/dl; lack of simultaneous emergency surgery or heart valve surgery. Exclusion criteria: Having underlying diseases (e.g., pulmonary, liver, kidney, thyroid, and digestive diseases); having history of open-heart surgery; fever; trauma; carotid artery involvement; sensitivity to insulin glargine.

Intervention groups

The intervention group will receive 0.1 units/kg glargine insulin 2 hours before the surgery. The patients will receive regular insulin intravenously during and after the surgery and subcutaneous injection regular subcutaneous insulin injection after the surgery. The control group will receive 0.1 cc normal saline 2 hours before the surgery. Regular insulin injection will be similar to the intervention group.

Main outcome variables

Evaluation and comparison of blood glucose will be

performed before the surgery, every 2 hours intraoperatively, and every 4-24 hours after the surgery in two groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130428013159N11**

Registration date: **2020-03-14, 1398/12/24**

Registration timing: **prospective**

Last update: **2020-03-14, 1398/12/24**

Update count: **0**

Registration date

2020-03-14, 1398/12/24

Registrant information

Name

Shima Sheybani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3764 7230

Email address

sheybanish@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-03, 1399/01/15

Expected recruitment end date

2021-04-04, 1400/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to compare the effectiveness of glargine insulin and regular insulin in hyperglycemic control among type II diabetic patients undergoing off-pump coronary artery bypass graft surgery

Public title

Effect of glargine insulin on hyperglycemic control in type II diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 35-75 years Sustaining ASA II Blood sugar of 150-300 mg/dl Lack of a simultaneous emergency surgery or heart valve surgery.

Exclusion criteria:

Having underlying diseases (e.g., pulmonary, liver, kidney, thyroid, and digestive diseases) Having history of open-heart surgery Fever Trauma Carotid artery involvement Sensitivity to insulin glargine

Age

From **35 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The subjects will be randomly assigned into two groups of 80 patients with www.sealedenvelope.com website. A noninvolved researcher will determine the random assignment sequencing base on block randomization. This site is designed that random assignment groups with no restriction.

Blinding (investigator's opinion)

Single blinded

Blinding description

Type II diabetic patients who are candidates for off-pump coronary artery bypass graft surgery at the Ghaem Hospital, Mashhad, Iran, are chosen. In this single-blind study, sealed opaque envelopes will be used to conceal the sequencing. The person responsible for data collection is blind to group allocation and the type of drugs.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Mashhad University of Medical Sciences

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9195965919

Approval date

2019-07-30, 1398/05/08

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.595

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

type II diabetic

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

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

Blood glucose

Timepoint

Before the surgery, every 2 hours intraoperatively, and every 4-24 hours after the surgery

Method of measurement

Glucose meter

Secondary outcomes

empty

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

The intervention group will receive 0.1 mg/kg units/kg glargine insulin 2 hours before the surgery. Based on the Van den Berghe national protocol, regular insulin

injection unit is equivalent to the blood glucose of patient divided by 150. The patients will receive these injections intravenously during and after the surgery. After the surgery, in the ICU, the blood glucose level of patient will be subtracted by 140; accordingly, each patient will receive 4 units of regular subcutaneous insulin injection for every 40.

Category

Treatment - Drugs

2**Description**

Control group: The control group will receive 0.1 cc normal saline 2 hours before the surgery. Based on the Van den Berghe national protocol, regular insulin injection unit is equivalent to the blood glucose of patient divided by 150. The patients will receive these injections intravenously during and after the surgery. After the surgery, in the ICU, the blood glucose level of patient will be subtracted by 140; accordingly, each patient will receive 4 units of regular subcutaneous insulin injection for every 40.

Category

Treatment - Drugs

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

Ghaem Hospital

Full name of responsible person

Shima Sheybani

Street address

Ghaem Hospital, Ahmadabad Street, Dr. Ali Shariati Square

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9176699199

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+98 51 3840 0000

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Sheybanish@mums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

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vcresearch@mums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Shima Sheybani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Ghaem Hospital, Ahmadabad Street, Dr. Ali Shariati Square

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The total data to be included are the primary and secondary effects to be shared.

When the data will become available and for how long

6 months after printing results

To whom data/document is available

Our data will only be available to researchers working in science center and university.

Under which criteria data/document could be used

Our data will be available for scholars working in science center and university.

From where data/document is obtainable

Shima Sheybani provides the analysis code to the applicants via email: Sheybanish@mums.ac.ir

What processes are involved for a request to access data/document

Applicants can respond to the email of the respondent and receive a response within a week.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Shima Sheybani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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