Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

A clinical trial to compare the effectiveness of glargine insulin and regular insulin in hyperglycemic control among type II diabetic patients undergoing on-pump coronary artery bypass graft before, during, and after the operation

Protocol summary

Study aim
The effectiveness of glargine insulin and regular insulin in hyperglycemic control among type II diabetic patients undergoing on-pump coronary artery bypass graft.

Design
Totally, 80 patients were chosen from the Ghaem Hospital. In this single-blind, controlled clinical trial, the patients are assigned into parallel groups using simple and successive sampling methods.

Settings and conduct
The patients at Ghaem Hospital 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 35-65 years; sustaining ASA II; blood sugar of 150-350 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 a history of open-heart surgery; fever; trauma; carotid artery involvement; sensitivity to insulin glargine

Intervention groups
The intervention group will receive 0.2 units/kg of glargine insulin 2 hours before the surgery. Based on the Van den Berghe national protocol, the regular insulin injection unit is equivalent to the blood glucose of patients 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 the patient will be subtracted by 140; accordingly, each patient will receive 4 units of regular subcutaneous insulin injection for every 40. The control group will receive 0.2 units/kg dextrose 5% 2 hours before the surgery. Regular insulin injection will be similar to the intervention group.

Main outcome variables
The comparison of blood glucose, long hospital days in ICU, type of antibiotic used, and wound dehiscence in control and intervention groups

General information

Reason for update
the wrong title

Acronym

IRCT registration information
IRCT registration number: **IRCT20130428013159N12**
Registration date: **2020-06-16, 1399/03/27**
Registration timing: **prospective**

Last update: **2020-07-11, 1399/04/21**
Update count: **1**

Registration date
2020-06-16, 1399/03/27

Registrant information

Name
Shima Sheybani
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 51 3764 7230
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2021-08-23, 1400/06/01

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 on-pump coronary artery bypass graft before, during, and after the operation

Public title

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

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 35-65 years Sustaining ASA II Blood sugar of 150-350 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 **65 years** old

Gender

Both

Phase

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 on-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

2020-02-18, 1398/11/29

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1399.076

Health conditions studied

1

Description of health condition studied

Type II diabetic

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

2

Description of health condition studied

Cardiovascular disease

ICD-10 code

I25

ICD-10 code description

Chronic ischaemic heart disease

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

1

Description
Long hospital days in ICU
Timepoint
After intervention
Method of measurement
The questionnaire

2

Description
Type of antibiotic used
Timepoint
After intervention
Method of measurement
The questionnaire

3

Description
Wound dehiscence
Timepoint
After intervention
Method of measurement
The questionnaire

Intervention groups

1

Description
Intervention group: The intervention group will receive 0.2 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 0.2 units/kg dextrose 5% 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
City
Mashhad
Province
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Postal code
9176699199
Phone
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Email
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
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 1538
Email
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

Street address

Ghaem Hospital, Ahmadabad Street, Dr. Ali Shariati Square

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Person responsible for scientific inquiries

Contact

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Mashhad University of Medical Sciences

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Yes - There is 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