Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The Comparison of the effects of metformin and insulin in the treatment of hyperglycemia after coronary artery bypass surgery in non diabetic patients.

Protocol summary

Summary

The purpose of this study is to compare the effect of metformin and insulin in the treatment of hyperglycemia after coronary artery bypass surgery in patients without diabetes. This research is a clinical trial. The study population is all the patients who will be undergone coronary artery bypass surgery in Kosar Hospital in Semnan. The main criterion for inclusion is having blood glucose higher than 150 mg/dl after coronary artery bypass surgery. The main criterion for exclusion is having a history of diabetes. The sample of 30 participants in each group and totally 60 people have been estimated. For this research, the patients' blood glucose will be assessed and recorded one hour before entering the operating room and three hours after the surgery. If a patient's postoperative blood glucose ishigher than 150 mg/dl,he will be enrolled. The table of random numbers will be used to place the patients in two groups of insulin and metformin. The patients who are placed in insulin group will receive continuous infusion insulin according to protocol of surgeons Thoracic Society (STS). The patients in metformingroup will receive a dose of 500 mg metformin tablet twice a day.In both groups, at first the patients' blood glucose will be controlled and recorded per hour and after the stabilization of blood glucose, it will be done every six hours. Then the difference between the initial blood glucose and calculated blood glucose will be calculated after intervention in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015072311399N2**
Registration date: **2015-08-04, 1394/05/13**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2015-08-04, 1394/05/13

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of the effects of metformin and insulin in the treatment of hyperglycemia after coronary artery bypass surgery in non diabetic patients.

Public title

The Comparison of the effects of metformin and insulin in

the treatment of hyperglycemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Glycosylated hemoglobin less than 7%; Blood glucose above 150 mg/dl; Elective coronary artery bypass surgery; Age between 35 to 75 years old; The use of cardiopulmonary bypass; Hemodynamically stable(BP>70 mmHg and PR between 50 and 110). Exclusion criteria: History of diabetes; GFR less than 60%; life-threatening arrhythmias; Prolonged intubation; The use of inotropic agents for hemodynamic stability; Potassium level higher than 5.5 or less than 3.5 on admission in ICU; Metabolic acidosis lower than 7.25 or lactate level higher than 4.5 mg/dl or BE less than 6 mmo/L; Pao 2 less than 60 mm Hg; The patient is NPO

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Semnan University Of Medical sience

Street address

Vice chancellor for research, Semnan University of Medical Sciences, Basij Blvd

City

Semnan

Postal code

Approval date

2015-07-28, 1394/05/06

Ethics committee reference number

IR.Semums.Rec.1394.69

Health conditions studied

1

Description of health condition studied

Hyperglycemia after coronary artery bypass surgery

ICD-10 code

197.1

ICD-10 code description

Other functional disturbances following cardiac surgery

2

Description of health condition studied

Hyperglycaemia

ICD-10 code

R73.9

ICD-10 code description

Hyperglycaemia, unspecified

Primary outcomes

1

Description

Blood Suger

Timepoint

Up to 6 hours after surgery each time and then every 6 hours

Method of measurement

Glucometer device

Secondary outcomes

1

Description

Lactat

Timepoint

Q 12 Hr

Method of measurement

Using of ABG machine

Intervention groups

1

Description

In the intervention group (1) or insulin group, patients will receive continuous insulin infusion according to the protocol of STS.After starting insulin infusion ,these patients’ blood glucose will be controlled per hour and according to their blood glucose level, the amount of insulin infusion will be continued.In this group blood glucose control interval will be every six hours after the stabilization of blood glucose. Then insulin infusion and six-hour blood glucose control will continue until the end of the third postoperative day (72 hours).

Category

Treatment - Drugs

2

Description
In the intervention group (2) or metformin group, the patients will receive metformin 500 mg twice a day and before the next dose of metformin, their blood glucose will be evaluated. If lactate is higher than 4/5 or 2 mmol higher than the previous response, takingmetformin will be stopped and the patient will be excluded.In these patients after starting metformintablet, their blood glucose will be controlled per hour and it will continue until the stabilization of blood glucose level.In this group the blood glucose interval control will be every six hours after the stabilization of blood glucose. Then, the prescription of metformin tablet of a dose of 500 mg twice a day and six-hour control of blood glucose until the end of the third postoperative day (72 hours) will continue.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar Hospital
Full name of responsible person
Dr Darush Pahlevan
Street address
1 th Floor, Vice chancellor for research, Kosar Hospital, Basij Blvd
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Semnan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Semnan University of Medical Sciences
Full name of responsible person
Dr Ali Rashidi-Pour
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Vice chancellor for research, Semnan University of Medical Sciences, Basij Blvd
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Semnan
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, Semnan 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

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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