

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 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 is higher 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 metformin group 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

Name

Abbasali Ebrahimian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3107 1082

Email address

ebrahimian.aa@gmail.com

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; Pao₂ 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

Ethics committee of Semnan University Of Medical science

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 Sugar

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, taking metformin will be stopped and the patient will be excluded. In these patients after starting metformin tablet, 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

City

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

Street address

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

City

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

Contact

Name of organization / entity

Semnan University of medical Sciences

Full name of responsible person

Abbas-Ali Ebrahimian

Position

Faculty member of Semnan University of medical Sciences

Other areas of specialty/work

Street address

Room #120, 1th floor, School of Nursing and Allied Health Sciences, Semnan University of medical Sciences, Km5 Damghan Road

City

Semnan

Postal code

Phone

+98 23 3365 4191

Fax

Email

aa.ebrahimian@semums.ac.irebrahimian.aa@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Kamran Ghods

Position

Specialist of heart surgery

Other areas of specialty/work

Street address

Kosae Hospital- basij Blvd

City

Semnan

Postal code

Phone

+98 23 3343 7825

Fax

Email

k.ghods@semums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Abbas-Ali Ebrahimian

Position

Faculty member of Semnan University of Medical Sciences

Other areas of specialty/work

Street address

Room #120, 1th floor, School of Nursing and Allied Health Sciences, Semnan University of medical Sciences, Km5 Damghan Road

City

Semnan

Postal code

Phone

+98 23 3365 4191

Fax

Email

aa.ebrahimian@semums.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