Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of blood sugar fluctuations in diabetic patients undergoing coronary artery bypass grafting; General anesthesia versus general anesthesia along with spinal anesthesia

Protocol summary

Summary

This study is a prospective and randomized double-blind clinical trial. The aim of this study is comparison of blood sugar fluctuations in diabetic patients undergoing coronary artery bypass grafting; general anesthesia versus general anesthesia along with spinal anesthesia. Total of sample size is 24 patient with ages: 50-65 years old. Inclusion criteria are diabetic patients candidate for coronary artery bypass surgery. The patients with heart block, cardiomegaly, kidney failure and hypothyroidism will be excluded. Patients are randomly divided into two groups with table of random numbers. Assessor of study and patients do not know about grouping people. Anesthesia induction in two groups is with 0.01 mg/kg midazolam, 3 mcg/kg fentanyl, 3 mg thiopental sodium and 0. 6 mg/kg atracurium. All two groups receives 0.5 mg/kg midazolam intramuscularly, half an hour before surgery. First group will go under general anesthesia. Second group will go under general anesthesia along with spinal anesthesia. Patients basic information such as age and sex, BMI will be recorded in all two groups. Blood pressure, heart rate and blood glucose before induction, five minutes after induction and once every 15 minutes during surgery will be recorded in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017040833300N1**
Registration date: **2017-04-23, 1396/02/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-04-23, 1396/02/03

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor For Research Of Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2017-01-01, 1395/10/12

Expected recruitment end date

2017-05-02, 1396/02/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of blood sugar fluctuations in diabetic patients undergoing coronary artery bypass grafting; General anesthesia versus general anesthesia along with spinal anesthesia

Public title

Comparison of blood sugar fluctuations in diabetic patients during heart surgery in the various methods of anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Diabetic patients candidate for coronary artery bypass surgery. Exclusion Criteria: Patients with EF less than 35; Heart block; Cardiomegaly; Kidney failure; and hypothyroidism.

Age

From **50 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double 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 Ahvaz Jundishapur University Of Medical Sciences

Street address

Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, Golestan BLvd., Ahvaz

City

Ahvaz

Postal code

Approval date

2016-12-31, 1395/10/11

Ethics committee reference number

IR.AJUMS.REC.1395.604

Health conditions studied

1

Description of health condition studied

Blood sugar changes

ICD-10 code

E16.0

ICD-10 code description

Drug-induced hypoglycaemia without coma

Primary outcomes

1

Description

Blood sugar

Timepoint

Before induction, five minutes after induction and once every 15 minutes during surgery

Method of measurement

Glucometer

Secondary outcomes

1

Description

Heart beat

Timepoint

During surgery

Method of measurement

Electrocardiogram

2

Description

Blood pressure

Timepoint

During surgery

Method of measurement

Sphygmomanometer

Intervention groups

1

Description

Control group: general anesthesia with 0.01 mg/kg midazolam, 3 mcg/kg fentanyl, 3 mg thiopental sodium and 0. 6 mg/kg atracurium.

Category

Treatment - Drugs

2

Description

Intervention group: Spinal anesthesia by intrathecal injection of 12.5 mg of marcaine 0.5 % with 50 mg of pethidine and then induction of general anesthesia (such as control group).

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Amir Salari

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Khomeini Hospital, ShahidAhwazian St., Ahwaz
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2

Recruitment center
Name of recruitment center
Golestan Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor For Research Of Ahvaz Jundishapur University of Medical Sciences
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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 Ahvaz Jundishapur 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