Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

The effects of dexmedetomidine on post-operative blood glucose level in non diabetic patients undergoing cardiac surgery

Protocol summary

Study aim

The effects of dexmedetomidine on post-operative blood glucose level in non diabetic patients undergoing cardiac surgery

Design

A clinical trial with the control group, with parallel groups, double-blind, randomized, phase 3 on 72 non-diabetic patients undergoing elective coronary artery surgery. Random sequence generation site www.sealedenvelope.com is used for randomization.

Settings and conduct

72 patients in Shahid Faghihi and Abu Ali Sina hospitals are divided into two groups (each group includes 36 people), group D (dexmedetomidine) and group C (control). After induction of anesthesia, infusion of dexmedetomidine at a dose of 0.5 µ g / kg/hr in group D and in the control group (C) normal saline 0.9% with the same volume will be started and continued until the end of surgery. And we measure their blood glucose levels before, during, and after the operation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Adult non-diabetic patients 40 to 80 years with EF more than 40% who are candidates for coronary artery bypass graft (CABG) surgery with informed written consent. exclusion criteria: emergency, valvular disorders, liver and kidney disease, steroid use, history of drug allergies, heart failure, acute myocardial infarction.

Intervention groups

Intervention group 1 (dexmedetomidine (D)) Continuous injection of dexmedetomidine made by EXIR Company at a dose of 0.5 µ g / kg / hr. By continuous infusion pump after induction of anesthesia, Intervention 2 (Control (C)) injection of normal saline 0.9% with the same amount.

Main outcome variables

Blood Glucose-potassium-mean arterial pressure-Heart rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180922041084N5**
Registration date: **2022-01-05, 1400/10/15**
Registration timing: **retrospective**

Last update: **2022-01-05, 1400/10/15**
Update count: **0**

Registration date

2022-01-05, 1400/10/15

Registrant information

Name

Maryam Tabibzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3628 1460

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dpt2370349433@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-12, 1400/06/21

Expected recruitment end date

2021-11-12, 1400/08/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of dexmedetomidine on post-operative blood glucose level in non diabetic patients undergoing cardiac surgery

Public title

The effects of dexmedetomidine on post-operative blood glucose level in non diabetic patients undergoing cardiac surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The Patients are Candidates for Coronary Artery Surgery (CABG). No history of diabetes. The patients 40 to 80 years of age Receive informed written consent EF more than 40%.

Exclusion criteria:

emergency surgery valvular heart disease liver and kidney dysfunction take steroids History of drug sensitivity heart failure Acute Myocardial Infarction

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use the limited randomization method of block randomization. The size of all blocks is equal and we will have 6 groups of 6 blocks (including 3 participants in the intervention group and 3 participants in the control group) in this two-group experiment. The randomization list is also taken from the random sequence generation site www.sealedenvelope.com, which is able to generate random sequences by blocking method.

Blinding (investigator's opinion)

Double blinded

Blinding description

Medications in 50cc syringes are prepared by a nurse anesthetist (who is not involved in the rest of the sample collection process) and the anesthesiologist and nurse anesthetist and ICU nurse who is responsible for monitoring and sampling the patient is not aware of the type of medication prescribed.

Placebo

Used

Assignment

Parallel

Other design features

change of blood glucose level during the surgery.The effects of dexmedetomidine on postoperative blood glucose level, measurement of potassium, blood pressure, and heart rate during surgery.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2020-05-20, 1399/02/31

Ethics committee reference number

IR.SUMS.MED.REC.1399.097

Health conditions studied

1

Description of health condition studied

Coronary Arteria Bypass Graft

ICD-10 code

Z95.1

ICD-10 code description

Presence of aortocoronary bypass graft

Primary outcomes

1

Description

Blood Glucose

Timepoint

Blood sugar before, during, and after surgery. Before induction of anesthesia, 15 minutes after induction of anesthesia, before the start of the cardiopulmonary pump, 30 minutes after the start of the cardiopulmonary pump, time of transfer to ICU 6 hours after transfer to ICU, 12 hours after transfer to ICU, and 24 hours after transfer to ICU.

Method of measurement

Check Blood glucose by glucometer.

Secondary outcomes

1

Description
Blood Potassium
Timepoint
Before induction of anesthesia (T0), 15 minutes after induction of anesthesia (T1), before the start of the cardiopulmonary pump (T2), 30 minutes after the start of the cardiopulmonary pump (T3), transfer time to ICU(T4), 6 hours after transfer to ICU (T5), 12 hours after transfer to ICU (T6), 24 hours after ICU transfer (T7).
Method of measurement
By blood gas.

2

Description
Check Heart rate
Timepoint
Before induction of anesthesia (T0), 15 minutes after induction of anesthesia (T1), before the start of the cardiopulmonary pump (T2), 30 minutes after the start of the cardiopulmonary pump (T3), transfer time to ICU(T4), 6 hours after transfer to ICU (T5), 12 hours after transfer to ICU (T6), 24 hours after ICU transfer (T7).
Method of measurement
By heart monitoring

3

Description
Mean Arterial blood pressure
Timepoint
transfer time to ICU(T4), 6 hours after transfer to ICU (T5), 12 hours after transfer to ICU (T6), 24 hours after ICU transfer (T7).
Method of measurement
Invasive arterial blood pressure monitoring.

Intervention groups

1

Description
Intervention group: Intervention group or group (dexmedetomidine (D)): In this group, continuous injection of dexmedetomidine made by ExIR Company at a dose of 0.5 µ g / kg/hr. It is infused by a continuous infusion pump after induction of anesthesia.
Category
Treatment - Drugs

2

Description
Control group: (control (C)) in this group injection of normal saline 0.9% at a dose of 0.5 µ g / kg / hr. It will be infused by a continuous infusion pump after induction of anesthesia.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Abu Ali Sina Hospital - Shahid Faghihi Hospital
Full name of responsible person
Mrs.Godarzi & Mr.parsaean
Street address
Shiraz - Sadra Town, Phase 2, Abu Ali Sina Hospital Shiraz, Zand Blvd., Shahid Faghihi Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr.Abas Rezaianzadeh
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Vcrdep@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Amirhosein Hasanzade

Position

Anesthesiology resident/physician

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Full name of responsible person

Simin Azemati

Position

Cardiac Anesthesiology Fellowship

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

MaryamTabibzadeh

Position

Medical Doctor

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

It is against our policy.

Study Protocol

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

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available