

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 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](http://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  $\mu$ 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  $\mu$ 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)

##### Phone

+98 71 3628 1460

##### Email address

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 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | pressure, and heart rate during surgery.       |                                                                                                                                                                                                                                                                                                                                                           |
| <b>Public title</b>                                                                                                      | The effects of dexmedetomidine on post-operative blood glucose level in non diabetic patients undergoing cardiac surgery                                                                                                                                                                                                                                                                                                                                                                               | <b>Secondary Ids</b>                           | empty                                                                                                                                                                                                                                                                                                                                                     |
| <b>Purpose</b>                                                                                                           | Treatment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <b>Ethics committees</b>                       |                                                                                                                                                                                                                                                                                                                                                           |
| <b>Inclusion/Exclusion criteria</b>                                                                                      | <b>Inclusion criteria:</b><br>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%.<br><b>Exclusion criteria:</b><br>emergency surgery valvular heart disease liver and kidney dysfunction take steroids History of drug sensitivity heart failure Acute Myocardial Infarction                                                                                                 | <u>1</u>                                       |                                                                                                                                                                                                                                                                                                                                                           |
| <b>Age</b>                                                                                                               | From <b>40 years</b> old to <b>80 years</b> old                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>Ethics committee</b>                        |                                                                                                                                                                                                                                                                                                                                                           |
| <b>Gender</b>                                                                                                            | Both                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <b>Name of ethics committee</b>                | Ethics Committee of Shiraz University of Medical Sciences                                                                                                                                                                                                                                                                                                 |
| <b>Phase</b>                                                                                                             | 3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <b>Street address</b>                          | Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street                                                                                                                                                                                                     |
| <b>Groups that have been masked</b>                                                                                      | <ul style="list-style-type: none"> <li>Participant</li> <li>Care provider</li> <li>Investigator</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                             | <b>City</b>                                    | Shiraz                                                                                                                                                                                                                                                                                                                                                    |
| <b>Sample size</b>                                                                                                       | Target sample size: <b>72</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <b>Province</b>                                | Fars                                                                                                                                                                                                                                                                                                                                                      |
| <b>Randomization (investigator's opinion)</b>                                                                            | Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <b>Postal code</b>                             | 7134814336                                                                                                                                                                                                                                                                                                                                                |
| <b>Randomization description</b>                                                                                         | 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 <a href="http://www.sealedenvelope.com">www.sealedenvelope.com</a> , which is able to generate random sequences by blocking method. | <b>Approval date</b>                           | 2020-05-20, 1399/02/31                                                                                                                                                                                                                                                                                                                                    |
| <b>Blinding (investigator's opinion)</b>                                                                                 | Double blinded                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Ethics committee reference number</b>       | IR.SUMS.MED.REC.1399.097                                                                                                                                                                                                                                                                                                                                  |
| <b>Blinding description</b>                                                                                              | 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.                                                                                                                                                                                         | <b>Health conditions studied</b>               |                                                                                                                                                                                                                                                                                                                                                           |
| <b>Placebo</b>                                                                                                           | Used                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <u>1</u>                                       |                                                                                                                                                                                                                                                                                                                                                           |
| <b>Assignment</b>                                                                                                        | Parallel                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Description of health condition studied</b> | Coronary Arteria Bypass Graft                                                                                                                                                                                                                                                                                                                             |
| <b>Other design features</b>                                                                                             | change of blood glucose level during the surgery.The effects of dexmedetomidine on postoperative blood glucose level, measurement of potassium, blood                                                                                                                                                                                                                                                                                                                                                  | <b>ICD-10 code</b>                             | Z95.1                                                                                                                                                                                                                                                                                                                                                     |
|                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>ICD-10 code description</b>                 | Presence of aortocoronary bypass graft                                                                                                                                                                                                                                                                                                                    |
|                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>Primary outcomes</b>                        |                                                                                                                                                                                                                                                                                                                                                           |
|                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <u>1</u>                                       |                                                                                                                                                                                                                                                                                                                                                           |
|                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>Description</b>                             | Blood Glucose                                                                                                                                                                                                                                                                                                                                             |
|                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>Timepoint</b>                               | 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. |
|                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>Method of measurement</b>                   | Check Blood glucose by glucometer.                                                                                                                                                                                                                                                                                                                        |
|                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>Secondary outcomes</b>                      |                                                                                                                                                                                                                                                                                                                                                           |

## 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  $\mu$ 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  $\mu$ 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.parsaeen

##### Street address

Shiraz - Sadra Town, Phase 2, Abu Ali Sina Hospital  
Shiraz, Zand Blvd., Shahid Faghihi Hospital

##### City

Shiraz

##### Province

Fars

##### Postal code

7199467985(بیمارستان)

##### Phone

+98 71 3235 1087

##### Fax

+98 71 3643 0038

##### Email

ga568881@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Dr.Abas Rezaianzadeh

##### Street address

Shiraz University of Medical Sciences

##### City

Shiraz

##### Province

Fars

##### Postal code

7134844119

##### Phone

+98 71 3234 9333

##### Fax

+98 71 3234 9333

##### Email

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

**Street address**

Anesthesiology Department, Faghihi Hospital, Zand  
Street

**City**

Shiraz

**Province**

Fars

**Postal code**

7134844119

**Phone**

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**Email**

A.hsanazade1367@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Simin Azemati

**Position**

Cardiac Anesthesiology Fellowship

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

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**City**

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**Province**

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**Postal code**

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**Email**

azemati@sums.ac.ir

## 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

**Street address**

Anesthesiology Department, Faghihi Hospital, Zand  
Street

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drtabib.maryam@yahoo.com

## 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