

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

The effect of perioperative Dexmedetomidine on renal function in patients undergoing CABG surgery and cardiopulmonary bypass

Protocol summary

Study aim

The effect of perioperative Dexmedetomidine on renal function in patients undergoing CABG surgery and cardiopulmonary bypass

Design

Double blinded randomized clinical trial

Settings and conduct

Patients in the dexmedmotidine group received doses of dexmedmotidine infusion at a dose of 0.5 micrograms / kg / h after induction of anesthesia until transmitted to ICU. Patients in the control group received normal saline infusion of the same volume in the intervention group after induction of anesthesia until transmitted to ICU.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age less than 70 years Patients undergoing coronary artery bypass graft surgery
Exclusion criteria: Emergency Surgery Redo Surgery Performing a coronary artery bypass graft surgery with other cardiac surgery Preoperative renal problems and serum creatinine levels higher than 1.4 Ejection fraction less than 40% Known liver problems or high levels of liver enzymes Using balloon pump inside aorta.

Intervention groups

Patients in the dexmedmotidine group received doses of dexmedmotidine infusion at a dose of 0.5 micrograms / kg / h after induction of anesthesia until transmitted to ICU. Patients in the control group received normal saline infusion of the same volume in the intervention group after induction of anesthesia until transmitted to ICU.

Main outcome variables

Serum creatinine level, Blood Urea Nitrogen, Glomerular filtration rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141009019470N83**

Registration date: **2019-07-08, 1398/04/17**

Registration timing: **prospective**

Last update: **2019-07-08, 1398/04/17**

Update count: **0**

Registration date

2019-07-08, 1398/04/17

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4270

Email address

masihif@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-11, 1398/04/20

Expected recruitment end date

2019-09-11, 1398/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of perioperative Dexmedetomidine on renal function in patients undergoing CABG surgery and cardiopulmonary bypass

Public title

The effect of perioperative Dexmedetomidine on renal

function in patients undergoing CABG surgery and cardiopulmonary bypass

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age less than 70 years Patients undergoing coronary artery bypass graft surgery

Exclusion criteria:

Emergency Surgery Redo Surgery Performing a coronary artery bypass graft surgery with other cardiac surgery Preoperative renal problems and serum creatinine levels higher than 1.4 Ejection fraction less than 40% Known liver problems or high levels of liver enzymes Using balloon pump inside aorta.

Age

To **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly assigned into two groups of intervention and control using the randomized table which is drives from randomozation.org.

Blinding (investigator's opinion)

Double blinded

Blinding description

Dexmedetomidine and placebo are being prepared by an anesthetist who is not involved in the next stages of the study.

Placebo

Used

Assignment

Parallel

Other design features

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

7134844119

Approval date

2019-03-31, 1398/01/11

Ethics committee reference number

IR.SUMS.REC.1398.015

Health conditions studied

1

Description of health condition studied

Coronary Artery Bypass Grafting surgery and cardiopulmonary bypass

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description

Serum creatinine level

Timepoint

Before surgery, on the first, second and third days after surgery in ICU

Method of measurement

Blood sample

2

Description

Blood Urea Nitrogen

Timepoint

Before surgery, on the first, second and third days after surgery in ICU

Method of measurement

Blood sample

3

Description

Glomerular filtration rate

Timepoint

Before surgery, on the first, second and third days after surgery in ICU

Method of measurement

Cockcroft-Gault Equation Formula

Secondary outcomes

1

Description

Inotropic Consumption in ICU

Timepoint

Before surgery, on the first, second and third days after surgery in ICU

Method of measurement

Observation

Intervention groups

1

Description

Intervention group: Patients in the dexmedmotidine group received doses of dexmedmotidine infusion at a dose of 0.5 micrograms / kg / h after induction of anesthesia until transmitted to ICU.

Category

Prevention

2

Description

Control group: Control group: Patients in the control group received normal saline infusion of the same volume in the intervention group after induction of anesthesia until transmitted to ICU.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi Hospital

Full name of responsible person

Rahim Hemati

Street address

Namazi Hospital, Namazi Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Younes Ghasemi

Street address

Vice chancellor of research, 7th floor of central building of Shiraz University of Medical Sciences,

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sacrc@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

Hamid Reza Lotfi

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Anesthesiology

Street address

Unit 4 No. 2, 19th Samaneh St, Ferdowsi Blvd.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mansoor Masjedi

Position

Cardiac Surgeon

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

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Anesthesiology Department, Faghihi Hospital, Zand Street

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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Farzaneh Masihi

Position

BS in anesthesia/English Consultant

Latest degree

Master

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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