

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Studying the effect of intraoperative dexmedetomidine infusion on acute renal failure in diabetic patients undergoing CABG surgery

Protocol summary

Study aim

Studying the effect of dexmedetomidine in reducing the incidence of AKI in diabetic patients receiving oral therapy during CABG surgery, On-Pump beating Study of changes in urea, creatinine, cardiac output, and GFR before, during, and after CABG surgery in the study groups. postoperative discharge rate, and duration of ventilatory support in the intensive care unit.

Design

Clinical trial with two groups of Dex and placebo by double blindness on 90 patients (Placebo 45 and Dex 45)

Settings and conduct

In Qaim Hospital in Mashhad, 60 diabetic patients are receiving Dex or placebo infusion from the time of admission until they are transferred to the ICU.

Participants/Inclusion and exclusion criteria

35 <age<70 years, EF > 35%, diabetes treated with medication, candidate for elective CABG On-Pump beating with two or more grafts, provided that one of the grafts is the LIMA, HR> 65 on admission, GFR>50, ASA class II, hematocrit > 30% No concomitant heart valve surgery, underlying diseases Exclusion criteria: Reoperations and non-coronary, CABG Off-Pump, patient sensitivity to dexmedetomidine family of drugs, return to operating room from ICU, history of previous cardiac surgery, history of fever, trauma, bilateral carotid artery stenosis > 50%, difficult or prolonged intubation > 20 seconds, body mass index > 30, HR < 65/min, LM > 50%, history of bundle branch block, history of treatment with clonidine or methylidopa, presence of IABP

Intervention groups

Dexmedetomidine infusion is started with an infusion pump in the dex group (dex diluted in saline at a concentration of 0.5 µg/kg/h) and in the placebo group, normal saline is started with an infusion pump at the same rate and continues until the end of the surgery.

Main outcome variables

Incidence of AKI in the first 48 hours after surgery in the ICU Creatinine and urea changes daily (on admission and

24 hours later) in the open heart ICU

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251013067605N1**

Registration date: **2025-10-19, 1404/07/27**

Registration timing: **prospective**

Last update: **2025-10-19, 1404/07/27**

Update count: **0**

Registration date

2025-10-19, 1404/07/27

Registrant information

Name

Islamic Republic of Iran Soolaki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4724 7769

Email address

www.mahsasoolaki75@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-11-24, 1404/09/03

Expected recruitment end date

2026-03-16, 1404/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Studying the effect of intraoperative dexmedetomidine infusion on acute renal failure in diabetic patients undergoing CABG surgery
Public title	Effect of Dexmedetomidine on Acute Renal Injury Patients undergoing CABG
Purpose	Prevention
Inclusion/Exclusion criteria	Inclusion criteria: EF>35% Diabetic patient treated with medication Candidate for Elective CABG On-Pump beating with two or more grafts, provided that one of the grafts is the left internal mammary artery (LIMA) HR > 65 on arrival GFR>50 ASA Class II classification Hct>30% The patient shouldn't have emergency surgery, concurrent valve surgery, or underlying renal, pulmonary, gastrointestinal, hepatic, or thyroid disease. Age between 35 to 70 Exclusion criteria: Reoperations and non-coronary procedures CABG Off-Pump Return to the operating room from the ICU History of previous heart surgery History of fever, trauma Bilateral carotid artery stenosis > 50% Intubation difficult or takes longer than 20 seconds BMI > 30 kg/m² HR>65 LM>50% History of bundle branch block History of treatment with clonidine or methylidopa IABP
Age	From 35 years old to 70 years old
Gender	Both
Phase	3
Groups that have been masked	- Participant - Outcome assessor
Sample size	Target sample size: 60
Randomization (investigator's opinion)	Not randomized
Randomization description	
Blinding (investigator's opinion)	Double blinded
Blinding description	Despite of giving informed consent, participants are unaware of whether they are receiving the drug or placebo. Similarly, the outcome assessor only sees and notes the outcomes and he is unaware of whether the patient received the drug or placebo.
Placebo	Used
Assignment	Parallel
Other design features	
Secondary Ids	empty

Ethics committees	
1	
Ethics committee	
Name of ethics committee	Imam Reza Hospital Educational, Research and Treatment Center - Mashhad University of Medical Scienc
Street address	Ahmadabad Boulevard, Qaim Hospital (AJ)
City	MASHHAD
Province	Razavi Khorasan
Postal code	9176697839
Approval date	2025-10-11, 1404/07/19
Ethics committee reference number	IR.MUMS.IRH.REC.1404.171
Health conditions studied	
1	
Description of health condition studied	Patients with diabetes treated with pills
ICD-10 code	N17.9
ICD-10 code description	Acute kidney failure, unspecified
Primary outcomes	
1	
Description	Incidence of postoperative AKI in diabetic patients undergoing CABG who received dexmedetomidine.
Timepoint	The incidence of AKI is determined by measuring urea and creatinine before, during, and after surgery.
Method of measurement	Blood test and urine output
Secondary outcomes	empty
Intervention groups	
1	
Description	Intervention group: Dexmedetomidine (Medonex) diluted in saline at a concentration of 0.5 micrograms/kg/hour) In the placebo group, normal saline solution was administered via an infusion pump at the same rate and continued until the end of the surgery.
Category	Prevention

2

Description

Control group: In the placebo group, 0.9% normal saline solution was administered by infusion pump at a rate of 0.5 micrograms/kg/hour, starting at the beginning of surgery and continuing until the end of surgery.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Qaem Hospital

Full name of responsible person

Mehdi Kahrom

Street address

Qaem Hospital, Ahmadabad Blvd

City

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9176697839

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Email

mahsasoolaki75@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Vakil Abad Blvd, Mashhad University of Medical Sciences

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Tafaghodim@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

DR. Mahdi Kahrom

Position

Cardiovascular Surgery Specialist

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Mehdi Kahrom

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

Dr.Mehdi Kahrom

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

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

Title and more details about the data/document

I have not yet decided yet, but if the data is requested by email to the corresponding author, the data will be made available to other researchers. The report of the end of the study project will be registered in the Mashhad University of Medical Sciences' researcher system; the resulting article will be published in reputable journals.

When the data will become available and for how long

If data is requested by email to the corresponding author, the data will be made available to other researchers within one week.

To whom data/document is available

Responsible author

Under which criteria data/document could be used

If the applicant has an approved proposal from one of the medical universities, the data will be made available to the researcher.

From where data/document is obtainable

Responsible author

What processes are involved for a request to access data/document

If data is requested by email to the corresponding author, the data will be made available to other researchers.

Comments