Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 methyldopa, 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 methyldopa 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 Bvld
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr.Mohsen Tafaghodi
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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 updating data

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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 y decided et, 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