

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Investigating the effect of dexmedetomidine drug infusion on hemodynamic changes and sedation after coronary bypass surgery (CABG) in opium addict patients

Protocol summary

Study aim

The purpose of this study is to investigate the effect of dexmedetomidine drug infusion on hemodynamic changes and sedation after coronary artery bypass surgery in opium addicted patients.

Design

Clinical trial with 3 groups, with factorial groups (including groups: a- dexmedetomidine with a dose of 0.2 µg/kg/h, b- normal saline with a dose of 0.2 µg/kg/h), double blind, randomized, phase 2 on 112 patients. People are assigned to two groups using a lottery.

Settings and conduct

Place: Heart ICU of Shafa Kerman Hospital, drugs will be given in the form of infusion. Due to the unconsciousness of the patient, one side will be blind by itself. The treatment regimen is also given by the nurse, and therefore, the researcher for analyzing sedation and hemodynamics and the person analyzer of the data will also be unaware of the treatment protocol. Therefore, the three strains are considered blind.

Participants/Inclusion and exclusion criteria

Clinical trial with 2 groups, with factorial groups (including groups: a- dexmedetomidine with a dose of 0.2 µg/kg/h, b- normal saline with a dose of 0.2 µg/kg/h), three-blind, randomized, phase 2 on 112 patients.

Intervention groups

A- Dexmedetomidine with a dose of 0.2 µg/kg/h B- normal saline with a dose of 0.2 µg/kg/h (control)

Main outcome variables

Hemodynamic changes, sedation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230825059256N1**

Registration date: **2023-09-07, 1402/06/16**

Registration timing: **prospective**

Last update: **2023-09-07, 1402/06/16**

Update count: **0**

Registration date

2023-09-07, 1402/06/16

Registrant information

Name

Arsalan Eskandari Damaneh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3214 1461

Email address

arsalaneskandaridamaneh55@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of dexmedetomidine drug infusion on hemodynamic changes and sedation after coronary bypass surgery (CABG) in opium addict patients

Public title

Investigating the effect of dexmedetomidine drug administration on hemodynamic changes and sedation after heart surgery in opium addicted patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Drug addiction (opium, methadone and syrup) based on DSM-V criteria
Patients undergoing on-pump heart surgery
Stable hemodynamics
Patients without cardiac pacemaker
Absence of liver and kidney disorders
Patients willing to participate in the study

Exclusion criteria:

Bradycardia with a rate less than 60 beats per minute
Unstable hemodynamics
People who need high-dose vasoconstrictor drugs
profuse bleeding
Disagreement to continue cooperation in the study by the first degree companions

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **112**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization, randomization by lottery, first, the number of samples A and B is written on paper and placed in a bag. After each patient's visit, a sheet from the selection bag and the type of treatment intervention written is assigned to that patient. This is done as many times as necessary for the selection sample.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study is conducted in a triple blind manner, the patient and the person who measures the final outcome and the statistical analysis do not know which group is the intervention group and receives the drug dexmedetomidine, and only the nurse of each patient knows about the patient receiving dexmedetomidine, and the control group receives normal saline infusion. And the person responsible for data registration has no knowledge, and web forms are registered as A.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Afzalipur Medical Education Center of Kerman University of Medical Scie

Street address

Afzalipur Medical Education Center, Imam Khomeini Highway (RA),Kerman,Iran,

City

Kerman

Province

Kerman

Postal code

7616913911

Approval date

2023-08-13, 1402/05/22

Ethics committee reference number

IR.KMU.AH.REC.1402.087

Health conditions studied

1

Description of health condition studied

Coronary artery bypass surgery

ICD-10 code

I25.0

ICD-10 code description

Atherosclerotic cardiovascular disease, so described

2

Description of health condition studied

addiction to opioid

ICD-10 code

F11.1

ICD-10 code description

Opioid abuse

Primary outcomes

1

Description

Hemodynamic changes

Timepoint

At the beginning, 3, 6, 8 and 12 hours after the operation

Method of measurement

Monitoring device

2

Description

relaxation

Timepoint

At the beginning, 3, 6, 8 and 12 hours after the operation

Method of measurement

modified Ramsay scores

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: receiving dexmedtomidinmin 0.2 µg/kg/h

Category

Treatment - Drugs

2

Description

Control group: receiving normal saline 0.2 µg/kg/h

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa hospital

Full name of responsible person

Hossein Sadeghi Gogheri

Street address

Shafa Medical Education Center, Kausar Blvd.,
Kerman, Iran

City

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Province

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76187751151

Phone

+98 34 3211 5780

Email

shafahospital@kmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abedin Iranpour

Street address

Research and technology department, at the
beginning of Ibn Sina street, Somayeh
Crossroads (Tahmasababad), Kerman

City

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Province

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7619813159

Phone

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Email

KMU_RESEARCH@YAHOO.COM

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Arsalan Eskandari Damaneh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Mahdieh Sharifzadeh

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

At the end of the study, part of the information including the effect of dexmedetomidine drug infusion on hemodynamic changes and sedation after coronary artery bypass surgery in opium addicted patients, after deidentifying the individuals, will be shared with those interested in the health field.

When the data will become available and for how long

2 to 6 months after data analysis

To whom data/document is available

Health researchers

Under which criteria data/document could be used

In order to use the results and during the written request

From where data/document is obtainable

Arsalan Eskandari- Email

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

The purpose of accessing data - requesting e-mail

Comments

Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Arsalan Eskandari Damaneh

Position

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