Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

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Iran (Islamic Republic of)

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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 opuim 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 opiod

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
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Research and technology department, at the beginning of Ibn Sina street, Somayeh Crossroads(Tahmasababad), Kerman
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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
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Position

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Latest degree

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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