

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

The effect of dexmedetomidine as adjuvant analgesia on postoperative delirium, and perioperative and postoperative arrhythmia and hemodynamics in opium user patients undergoing open heart surgery

Protocol summary

Study aim

The effect of dexmedetomidine as adjuvant analgesia on delirium and perioperative and postoperative arrhythmia and hemodynamics in opium user patients undergoing open heart surgery

Design

This is a prospective randomized clinical trial study on patients with a history of opioid addiction who are candidates for cardiac bypass surgery under general anesthesia in the operating room of Kausar Semnan Hospital.

Settings and conduct

kosar hospital, semnan

Participants/Inclusion and exclusion criteria

Inclusion criteria history of opioim addiction Elective heart surgery candidate Exclusion criteria Weight less than 50 kg History of head trauma or neurological lesions Liver failure History of allergy to dexdetomidine Patients with cardiac EF below 30% Patients who need an intra-aortic balloon pump Any unforeseen conditions and malfunction of the pump occur during surgery Clamping of the aorta takes more than 2 hours Patients with a history of stroke Patients should have any disorder of level of consciousness before the operation Patients have a history of congestive heart failure Patients with chronic renal failure or history of dialysis History of arrhythmia or heart surgery in the past Lack of informed consent

Intervention groups

An intraoperative group plus common anesthesia protocol, loading dose: 6mcg/kg/hr intravenous dexmedetomidine with maintenance drip of 0.2 mcg/kg/hour- 1 mcg/kg/hour will be injected.

Main outcome variables

delirium cognitive function arrhythmia hemodynamics

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230603058373N1**

Registration date: **2023-12-14, 1402/09/23**

Registration timing: **registered_while_recruiting**

Last update: **2023-12-14, 1402/09/23**

Update count: **0**

Registration date

2023-12-14, 1402/09/23

Registrant information

Name

Kiarash Roustai geraylow

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2285 8706

Email address

k.roustai@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-12, 1402/09/21

Expected recruitment end date

2024-01-21, 1402/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of dexmedetomidine as adjuvant analgesia on postoperative delirium, and perioperative and postoperative arrhythmia and hemodynamics in opium user patients undergoing open heart surgery

Public title

The effect of dexmedetomidine as adjuvant analgesia on postoperative delirium, and perioperative and postoperative arrhythmia and hemodynamics in opium user patients undergoing open heart surgery

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

history of opium addiction candidate for elective open heart surgery

Exclusion criteria:

weight<50kg history of trauma or neurological lesions liver failure dexmedetomidine allergy EF<30% aortic pump requirement any unpredictable circumstances or pump failure during surgery aortic clamp>2h history of cerebral stroke Impaired level of consciousness history of heart failure kidney failure or history of dialysis

Age

No age limit

Gender

Both

Phase

4

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

These patients were randomized into two groups using permuted block randomization with 6 blocks (these patients are matched in terms of gender and age ± 5 years). .

Blinding (investigator's opinion)

Triple blinded

Blinding description

In order to place the research units in two control and intervention groups and to create a random sequence, sealed envelopes were used. In this way, inside half of the envelopes, the letter c meaning the control group and inside the other half, the letter I meaning the intervention group. Then, each of the research units was asked to select an envelope to determine which group they belong to. The participant and the outcome evaluators and dsmb were unaware of the assigned group.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Semnan University Of Medical Sciences and Health Services

Street address

Headquarter of Semnan University of Medical Sciences and Health Services, Bassij Blvd, Semnan, Iran.

City

semnan

Province

Semnan

Postal code

35147-99442

Approval date

2023-03-13, 1401/12/22

Ethics committee reference number

IR.SEMUMS.REC.1401.307

2**Ethics committee****Name of ethics committee**

Research Ethics Committees of Semnan University Of Medical Sciences and Health Services

Street address

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Health conditions studied**1****Description of health condition studied**

post operative delirium

ICD-10 code

F05.8

ICD-10 code description

Other delirium

2

Description of health condition studied

cardiac surgery complications

ICD-10 code

T82.9

ICD-10 code description

Unspecified complication of cardiac and vascular prosthetic device, implant and graft

Primary outcomes

1

Description

delirium

Timepoint

daily

Method of measurement

confusion assessment method

2

Description

arrhythmia

Timepoint

perioperative and postoperative

Method of measurement

checklist

Secondary outcomes

1

Description

postoperative pain

Timepoint

every 4h

Method of measurement

visual analog scale

2

Description

cognitive function

Timepoint

preoperative and postoperative

Method of measurement

mini mental state exam

Intervention groups

1

Description

Intervention group: In the intervention group, in addition to the common anesthesia protocol, loading dose: 6 mcg/kg/hr intravenous dexmedetomidine with maintenance drip of 0.2 mcg/kg/hour - 1 mcg/kg/hour will be injected.

Category

Treatment - Drugs

2

Description

Control group: common anesthesia protocol

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar hospital

Full name of responsible person

Mohammad Forozashfard

Street address

Amin street, Nirogah square, Golestan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Majid Mirmohammadkhani

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Semnan University of Medical Sciences

Proportion provided by this source

10

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
Semnan University of Medical Sciences
Full name of responsible person
Mohammad Foroozeshfard
Position
professor
Latest degree
Specialist
Other areas of specialty/work
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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

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