Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Effect of perioperative dexmedetomidine infusion on post operative delirium in on pump heart surgery patients

Protocol summary

Study aim
The effect of dexmedetomidine infusion during cardiac surgery on reducing the prevalence of postoperative delirium

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, on 60 patients. Random numbers in Excel software are used for randomization

Settings and conduct
The study was performed in a double-blind manner at Modarres Hospital and on patients undergoing heart surgery. The Intensivist who measure patient delirium is not aware of the study groups. Only the physician responsible for the patient's anesthesia knows that the perfused drug may be Dex and may consider the patient's possible hemodynamic and bradycardia complications

Participants/Inclusion and exclusion criteria
Adult patients referred to the cardiac operating room Inclusion criteria: 1- Age between 40 to 80 years 2- EF above 20% Exclusion criteria: 1- Known allergy to dexmedetomidine 2- Taking preoperative antipsychotic drugs 3- Patient's lack of cooperation 4- History of delirium, neuropsychiatric illness and seizures 5- Emergency operation

Intervention groups
Group receiving dexmedetomine infusion during cardiac surgery and group receiving normal saline infusion as placebo

Main outcome variables
Measurement of postoperative delirium based on Richmond's Agitation- sedation scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180724040575N4**
Registration date: **2020-10-05, 1399/07/14**
Registration timing: **retrospective**

Last update: **2020-10-05, 1399/07/14**
Update count: **0**

Registration date
2020-10-05, 1399/07/14

Registrant information

Name
kamal fani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2207 4095

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kamalfani@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-03-21, 1398/01/01

Expected recruitment end date
2019-06-21, 1398/03/31

Actual recruitment start date
2019-04-21, 1398/02/01

Actual recruitment end date
2019-08-18, 1398/05/27

Trial completion date
2019-08-21, 1398/05/30

Scientific title
Effect of perioperative dexmedetomidine infusion on post operative delirium in on pump heart surgery patients

Public title
Effect of dexmedetomine on delirium

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adults candidate for cardiac surgery Ejection Fraction(EF) >20%

Exclusion criteria:

Known allergy to dexmedetomidine Taking preoperative antipsychotic drugs Lack of patient cooperation and satisfaction History of delirium, neuropsychiatric disorders and seizures Emergency operation

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

For assignment in intervention and control groups, a simple randomization method with the help of random numbers of Excel software is used. With the help of the RANDBETWEEN function, we create a column consisting of 30 random numbers between 1 and 60, and by removing duplicate items, we continue this function until the complete production of 30 random numbers. These numbers are the row of participants who are in the intervention group, and naturally the row of numbers that are not in this list of 30 are in the control group. For each row of participants, a closed envelope is prepared by the researcher not present in the operating room, and with the arrival of each patient, the relevant envelope is opened by the project partner in the operating room and the designated group is determined.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants are not aware of the administration of the drug or placebo infused during anesthesia. Data collector are also unaware of the study group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of shahid beheshti University of Medical Sciences

Street address

Taleghani Hospital , Velenjak Ave., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985711151

Approval date

2019-09-18, 1398/06/27

Ethics committee reference number

IR.SBMU.RETECH.REC.1398.332

Health conditions studied

1

Description of health condition studied

Delirium

ICD-10 code

F05

ICD-10 code description

Delirium due to known physiological condition

Primary outcomes

1

Description

Delirium score based on Richmond Agitation Sedation Scale

Timepoint

Evaluation of delirium based on Richmond score before , 6 and 24 h after surgery

Method of measurement

Richmond Agitation Sedation Scale (RASS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, after induction of anesthesia, dex medetomidine at a dose of 0.2 to 0.5 micrograms per kilogram per hour is started as an intravenous infusion and continues until the sternum closes at the end of the operation. Dexmedetomidine made by Exir Company is used with an initial concentration of 200 micrograms in 2 ml, which is dissolved in 50 ml of normal saline made by Shahid Ghazi serum manufacturing company and will be used with a final concentration of 4 micrograms per ml.

syringe Pump and 50 ml syringe are used for infusion.

Category

Treatment - Drugs

2

Description

Control group: In this group, after induction of anesthesia, normal saline serum at a dose of 0.1 ml / kg / h is started as an intravenous infusion and continues until the sternum is closed at the end of the operation. Normal saline is prepared in 50 ml syringe and the infusion is performed by a pump syringe.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Modarres Hospital

Full name of responsible person

Kamal Fani

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Taleghani Hospital , Velenjak Ave., Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarqhi

Street address

Shahid Chamran Highway - Yemen St. - Shahid Abbas Arabi St. (Parvaneh) - Next to Taleghani Hospital - Shahid Beheshti University of Medical Sciences - Headquarters Building 2- Floor 5- Deputy of Research and Technology

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Kamal Fani

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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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