Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Studying the effects of dexmedetomidine on clinical outcomes and renal function after heart surgery

Protocol summary

Study aim
The aim of the current study is to investigate the effects of dexmedetomidine medication on clinical outcomes and renal function following cardiac surgeries.

Design
Controlled clinical trial, parallel groups, double-blinded, randomized

Settings and conduct
This study is to be conducted in the Rajaie Cardiovascular Center at Tehran, Iran. The study includes two parallel randomly-assigned groups of low and high dose dexmedetomidine. Patients and the outcome assessors are blinded to the allocation groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age over 18 years old, candidacy for open heart surgery with cardiopulmonary bypass, informed consent for participation in the study Exclusion criteria: History of severe renal disease or renal failure, history of inflammatory or autoimmune disease

Intervention groups
Control group receiving low dose Pfizer company's dexmedetomidine (0.5 ug/kg/hr) continuously once from anesthesia induction till the end of operation; Treatment group receiving high dose Pfizer company'sdexmedetomidine (0.75 ug/kg/hr) continuously once from anesthesia induction till the end of operation

Main outcome variables
Hemodynamic condition, urine output, blood urea nitrogen and creatinine, mechanical ventilation time and intensive care unit stay, operation and cardiopulmonary bypass duration, blood and blood products need, inotrope need, diuretic needs in operation room and intensive care unit

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170912036157N1**
Registration date: **2019-07-30, 1398/05/08**
Registration timing: **retrospective**

Last update: **2019-07-30, 1398/05/08**
Update count: **0**

Registration date
2019-07-30, 1398/05/08

Registrant information

Name
Ziae Totonchi

Name of organization / entity
IUMS

Country
Iran (Islamic Republic of)

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+98 21 2392 2153

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totonchi@rhc.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-03-20, 1395/12/30

Expected recruitment end date
2019-05-21, 1398/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Studying the effects of dexmedetomidine on clinical outcomes and renal function after heart surgery

Public title
Effects of dexmedetomidine drug in heart surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Informed consent for participation Elective open heart surgery on cardiopulmonary bypass Age over 18 years
Exclusion criteria:
Background of preexisting inflammatory disease history of preexisting renal insufficiency or severe renal disease before operation
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **88**
Randomization (investigator's opinion)
Randomized
Randomization description
For randomization, researchers use the Stratified Block randomization method and randomize blocks of 3 to 4 people, and the Random Number Generator as the randomization tool. The method of making random sequences is also stratified according to the inotropic drug intake. To conceal the study from the patient and the main physician of the study (double-blind), the allocation of subjects and drugs in the two groups is done by a trained anesthetic technician that records all the cases initially and the final evaluator of the patient has no information on the type of the prescribed drug. Finally, the statistical information of the two groups is given to the analyst, which is not blind to the groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients are unaware of the groups they were allocated into. They receive the medication during anesthesia. Assessment of the target outcomes are performed with the trained nursing staff who are unaware of the groups. Outcome assessors who fill the questionnaires are not informed regarding the patient allocation.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Comittee, Rajaie Cardiovascular Medical and Research Center, Iran University of Medical Scien
Street address
Valiasr Cross., Hashemi-Rafsanjani Exp.
City
Tehran
Province
Tehran
Postal code
1416771818
Approval date
2018-07-23, 1397/05/01
Ethics committee reference number
IR.RHC.REC.1397.052

Health conditions studied

1

Description of health condition studied
Coronary artery bypass grafting
ICD-10 code
I25.4
ICD-10 code description
Coronary artery aneurysm and dissection

2

Description of health condition studied
Aneurysms of the cardiac arteries
ICD-10 code
I71
ICD-10 code description
Aortic aneurysm and dissection

Primary outcomes

1

Description
Systolic blood pressure
Timepoint
Before operation and 6, 12, 24 and 48 hours after operation
Method of measurement
Vital sign monitoring system

2

Description
Urine output
Timepoint
During cardiopulmonary bypass and 24 and 48 hours after transfer to intensive care unit
Method of measurement
Urine volume measurement

3

Description
Blood urea nitrogen (BUN)
Timepoint
Before operation and 24, 48 and 72 hours after operation
Method of measurement
Auto-analyzer

4

Description
Mechanical ventilation time
Timepoint
During operation and intensive care unit stay
Method of measurement
Recording the time

5

Description
Blood and blood products transfusion
Timepoint
In operation room and 48 hours after operation
Method of measurement
Recording the amount received

6

Description
Inotrope medicines
Timepoint
In the operation room and until 48 hours post-operation
Method of measurement
Recording the administered amount

7

Description
Diuretics
Timepoint
In the operation room and intensive care unit
Method of measurement
Recording the administered amounts

8

Description
Systolic blood pressure
Timepoint
Before operation and 6, 12, 24 and 48 hours after operation
Method of measurement
Vital sign monitoring system

9

Description
Mean arterial blood pressure
Timepoint
Before operation and 6, 12, 24 and 48 hours after operation
Method of measurement
Vital sign monitoring system

10

Description
Creatinine
Timepoint
Before operation and 24, 48 and 72 hours after operation
Method of measurement
Auto-analyzer

11

Description
Intensive care unit (ICU) stay
Timepoint
During Intensive care unit (ICU) stay
Method of measurement
Recording the time

12

Description
Operation time
Timepoint
During operation
Method of measurement
Recording the time

13

Description
Cardiopulmonary bypass (CPB) duration
Timepoint
During CPB
Method of measurement
Recording the time

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: High-dose Pfizer company dexmedetomidine (0.75 ug/kg/hr) once from anesthesia induction till the end of operation
Category
Treatment - Drugs

2

Description
Control group: Low dose Pfizer company dexmedetomidine (0.5 ug/kg/hr) once from anesthesia induction till the end of operation
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Rajaie Cardiovascular Medial and Research Center

Full name of responsible person
Ziya Totonchi

Street address
Valiasr cross., Hashemi-Rafsanjani Exp.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Dean of Research, Rajaie Cardiovascular Medical and Research Center

Full name of responsible person
Majid Haghjoo

Street address
Hashemi-Rafsanjani Exp., Valiasr cross.

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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
Dean of Research, Rajaie Cardiovascular Medical and Research Center

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
Rajaie Cardiovascular Medical and Research Center

Full name of responsible person
Ziae Totonchi

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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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