Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A Comparative Study on the Effect of Prescribing Dexmedetomidine with Haloperidol in Preventing Delirium after Coronary Artery Bypass Graft surgery in Chamran Hospital، 2016-2017

Protocol summary

Study aim

1) Determining and comparing delirium incidence in two groups that receive dexmedetomidine and haloperidol 2) Determining and comparing the severity of delirium incidence in two groups that receive dexmedetomidine and haloperidol 3) Determining the average necessary dose of medicine used in two groups of dexmedetomidine and haloperidol, and comparing them 4) Determining the average time length of prescribing medicine used in two groups of dexmedetomidine and haloperidol, and comparing them 5) Determining and comparing the frequency distribution of medicine side effects in two groups of dexmedetomidine and haloperidol, and comparing them 6) Determining and comparing the average time of patients' hospitalization in two groups of dexmedetomidine and haloperidol, and comparing them 7) Determining and comparing the average patients' sedation in two groups of dexmedetomidine and haloperidol, and comparing them 8) Determining and comparing the average time length of intubation and extubation in two groups

Design

The patients of this study include all the candidate patients who referred to Shahid Chamran Hospital for coronary artery bypass graft surgery. The volume of sample needed for this study was calculated using the formula of estimating sample volume for prevalence studies. The confidence level was considered 95%, and the agitation prevalence after open surgery of coronary arteries was considered 0.5 due to the lack of similar study which resulted in 44 people in each group. The possibility of collapse in each group was 50 people. Sampling was done as non-probable and random.

Settings and conduct

After necessary fixing, the candidate patients for open surgery of coronary arteries were selected by referring the investigator to Shahid Chamran Hospital, and after getting their permission to participate in the study, their demographic information, history of diabetes and blood pressure, addiction to cigarettes and drugs and alcohol, and history of psychiatric drugs' usage was registered in the questionnaire provided for this purpose and entered in the data gathering form. Also the most recent amount of hemoglobin, WBC, and creatinine of the patients before the surgery were extracted of their medical file and registered. The patients were put into two groups of intervention and control randomly.

Participants/Inclusion and exclusion criteria

The entrance criterion: included the 18 to 80 year old; patients who were candidates for open surgery of coronary arteries and referred to Shahid Chamran Hospital; The candidates had agreed to participate in the study; and were free from any psychiatric disease or dementia. The exit criterion: included lack of candidate's assistance; shortages in data under study; the patient's death during the surgery or by entrance to ICU; need to do the surgery again due to bleeding after entrance to ICU; excessive allergy to haloperidol and phenothiazine; Parkinson (trembling at the time of rest) and weakness in CNS; glaucoma; seizure anamnesis; getting anti-seizure; anti-Parkinson، or lithium drugs.

Intervention groups

The intervention group were put under dexmedetomidine 1 microgram per kilogram during 10 minutes and preserver infusion of 0.2 to 0.7 Micrograms per hour per kilogram. The control group were put under intramuscular haloperidol 0.5 milligram. In the case of agitation incidence, both groups received treatment dose of haloperidol (0.5 milligram intramuscular).

Main outcome variables

The incidence of deliriu، the severity of delirium، the required dosage of medications، the average length of hospitalization، the frequency distribution of drug complications، the mean sedation، the mean duration of intubation and extubation of patients after cardiac surgery in the two groups receiving dexmedetomidine

and haloperidol will be different.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171104037209N1**
Registration date: **2017-11-29, 1396/09/08**
Registration timing: **retrospective**

Last update: **2017-11-29, 1396/09/08**
Update count: **0**

Registration date

2017-11-29, 1396/09/08

Registrant information

Name

shima khamesipour

Name of organization / entity

Isfahan School of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 32403150

Email address

massoumigh@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

govermental and company

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparative Study on the Effect of Prescribing Dexmedetomidine with Haloperidol in Preventing Delirium after Coronary Artery Bypass Graft surgery in Chamran Hospital، 2016-2017

Public title

A Comparative Study on the Effect of Prescribing Dexmedetomidine with Haloperidol in Preventing Delirium

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

The entrance criterion included the patients who were candidates for open surgery of coronary arteries and referred to Shahid Chamran Hospital participate in the study And were free from any psychiatric disease or dementia He candidates had agreed to participate in the study

Exclusion criteria:

lack of candidate’s assistance Shortages in data under study The patient’s death during the surgery or by entrance to ICU Need to do the surgery again due to bleeding after entrance to ICU Excessive allergy to haloperidol and phenothiazine Parkinson (trembling at the time of rest) and weakness in CNS Glaucoma Seizure anamnesis Getting anti-seizure, anti-Parkinson, or lithium drugs

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

We made patients aware of the intervention، but without knowing which drug they would receive، each patient was given a number، According to even or odd receive either dexmedetomidin or haloperidol

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan School of Medical Sciences

Street address

Thousand Jereeb St. Isfahan University of Medical Sciences and Health Services, Faculty of Medicine

City

esfahan

Province

Isfehan

Postal code

81746-73461

Approval date

2016-02-24, 1394/12/05

Ethics committee reference number
ir.mui.rec.1395.3.214

Health conditions studied

1

Description of health condition studied
Delirium
ICD-10 code
F05.8
ICD-10 code description
Other delirium Delirium of mixed origin Postoperative delirium

Primary outcomes

1

Description
Delirium، Delirium Exposure، Blood Pressure، During Hospital Occupation، Laboratory variables (sodium and potassium، and variables ABG)
Timepoint
Before entering ICU، Before the pump، During the pump، After the pump، The first day of the ICU، The second day of the ICU، Third day of the ICU
Method of measurement
Delirium demonstration by the Richmond Agitation-Sedation Scale Severity of delirium using CAM-ICU Duration of the pump in minutes using the timer The duration of admission to the ICU by day using the count of the days Average arterial blood pressure using a mercury pressure gauge device Receiving haloperidol in the event of delirium with patient file information The amount of pack cell received using patient file information Laboratory variables through blood sampling and determination of laboratory values

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: were put under dexmedetomidine 1 microgram per kilogram during 10 minutes and preserver infusion of 0.2 to 0.7 Micrograms per hour per kilogram until the separation of the ventilator andwere put under intramuscular haloperidol 0.5 mil
Category
Treatment - Drugs

2

Description
Control group: were put under intramuscular haloperidol 0.5 milligram in case of agitation
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Educational، therapeutic and research center of Shahid Chamran heart
Full name of responsible person
Dr. Gholamreza Masoumi، Dr. Mojtaba Mansouri
Street address
Third moshtagh st، bozorgmehr bridge، shahid chamran cardiology hospital
City
Esfahan
Province
Isfehan
Postal code
8166173414
Phone
+98 31 3260 0961
Email
massoumigh@mui.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr Ahmad movahedian atar
Street address
hezar jarib st, Isfahan University of Medical Sciences and
City
esfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3668 8138
Fax
+98 31 3668 7898
Email
research@mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
50
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
Esfahan University of Medical Sciences
Full name of responsible person
Dr Gholamreza Masoumi
Position
Associate Professor, Department of Anesthesiology, Isfahan University of Medical Sciences
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Third moshtagh st, bozorgmehr bridge, shahid chamran hospital
City
esfahan
Province
Isfehan
Postal code
8166173414
Phone
+98 31 3260 0961
Fax
Email
massoumigh@mui.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr Gholamreza Masoumi
Position
Associate Professor, Department of Anesthesiology, Isfahan University of Medical Sciences
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Third moshtagh st, bozorgmehr bridge , Chamran Heart Hospital
City
esfahan
Province
Isfehan
Postal code
8166173414
Phone
+98 31 3260 0961
Fax
Email
massoumigh@mui.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr Gholamreza Masoumi
Position
Associate Professor, Department of Anesthesiology, Isfahan University of Medical Sciences
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Third moshtagh st, bozorgmehr bridge, Chamran Heart Hospital
City
esfahan
Province
Isfehan
Postal code
8166173414
Phone
+98 31 3260 0961
Fax
Email
massoumigh@mui.ac.ir
Web page address

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