# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

04 Jul 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
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**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
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Esfahan University of Medical Sciences
**Full name of responsible person**
Dr Ahmad movahedian atar
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hezar jarib st, Isfahan University of Medical Sciences and
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**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
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## Person responsible for scientific inquiries

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**Latest degree**
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## Person responsible for updating data

**Contact**
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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