# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

01 Jun 2026

## Comparison of outcomes between Propofol and Dexmedetomidine on extubation time and vital signs in patients with post- coronary artery bypass grafting in Open heart Intensive Care Unit

## Protocol summary

**Study aim**

Overall Aim is to compare the effect of Dexmedetomidine and Propofol on extubation time and vital signs in patients undergoing coronary artery bypass grafting in the Intensive Care Unit Open Heart.The practical goal of this project is to select the right medication for sedation of post-CABG patients with fewer side effects, more efficient and more suitable for extubation.

**Design**

Clinical trial with a total of two parallel and equal groups, double-blind, randomized, on 92 patients. A block method was used for randomization

**Settings and conduct**

CABG candidate patients who are referred to Amirul Mominin Arak Hospital.Double-blind collection of vital signs and other variables. The patients are divided into two groups by anesthesiologist so the patient and the evaluator are not aware of the drug's name used in the groups

**Participants/Inclusion and exclusion criteria**

Terms and conditions of participation: Having informed consent Patients must meet inclusion criteria, i.e. be elective and referred for open heart surgery only.Age should be between 35 and 80 years old.Performed by the same surgeon.The maximum duration of the surgery must be 6 hours.All were operated with a cardiopulmonary pump.Valve surgery should not be performed at the same time as CABG Exclusion conditions are: Patient is not a candidate for elective CABG surgery.Duration of surgery is more than 6 hours.Patients have not had surgery outside of the cardiopulmonary pump.Patients outside the 35-80 age range.The patient has the right to withdraw at any stage of the research

**Intervention groups**

Two equal groups of 46 people. One group receives propofol medication and the other group receives dexmedetomidine medication, then the effect of these two medications on these two groups is measured.

**Main outcome variables**

Mean Arterial Pressure Pulse rate SpO2 Extubation time Hospitalization time Department hospitalization time

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20240207060924N1**
Registration date: **2024-02-17, 1402/11/28**
Registration timing: **prospective**

Last update: **2024-02-17, 1402/11/28**
Update count: **0**

**Registration date**

2024-02-17, 1402/11/28

**Registrant information**

**Name**

Taha Rafiei

**Name of organization / entity**

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Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2024-02-20, 1402/12/01

**Expected recruitment end date**

2024-11-21, 1403/09/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of outcomes between Propofol and Dexmedetomidine on extubation time and vital signs in patients with post- coronary artery bypass grafting in Open heart Intensive Care Unit

**Public title**

Effect of Propofol in coronary bypass surgery

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Having informed consent Patients must meet inclusion criteria, i.e. be elective and referred for open heart surgery only Age should be between 35 and 80 years old Performed by the same surgeon The maximum duration of the surgery must be 6 hours All were operated with a cardiopulmonary pump Valve surgery should not be performed at the same time as CABG

**Exclusion criteria:**

Patient is not a candidate for elective CABG surgery Duration of surgery is more than 6 hours Patients have not had surgery outside of the cardiopulmonary pump Patients outside the 35-80 age range The patient has the right to withdraw at any stage of the research

**Age**

From **35 years** old to **80 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **92**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, we will randomly divide 92 patients into two equal groups (P) and (D) using random block method. The randomization unit will be done individually and we will use statistical software as a tool. All statistical combinations that these two groups can have will be written. These combinations will include PPDD, PDDP, PDPD, DDPP, DPDP, DPPD. Now, using these combinations, the observations are placed into two intervention groups. Note that the intervention groups are chosen blindly.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The aforementioned study is a double-blind study in which patients who meet the inclusion criteria and provide informed consent are assigned to one of two groups receiving Propofol (P) or Dexmedetomidine (D). Patients are randomized into groups (P) and (D) by the anesthesiologist and are unaware of which group they are in. In addition, the intern in charge of the project does not know the names of the groups. After the patients wake up and become conscious and are extubated while the sedative infusion is stopped, the student in charge of the project will be present in the ward to fill in the questionnaires, so he will not know about the studied groups and will be blinded.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Arak University of Medical Sciences

**Street address**

Basij square, sardasht, Arak university of medical science

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Markazi

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3819693345

**Approval date**

2024-02-07, 1402/11/18

**Ethics committee reference number**

IR.ARAKMU.REC.1402.212

## Health conditions studied

### 1

**Description of health condition studied**

Comparison of Outcomes Between Propofol and Dexmedetomidine in Post-Coronary Artery Bypass Graft Patients

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**

Mean arterial blood pressure

**Timepoint**

Measurement of mean arterial blood pressure at 5, 15, 30, 45, 60, 90, 120, 150 minutes after entering the ward

**Method of measurement**

Pulse Oximeter

**2**

**Description**

Pulse rate

**Timepoint**

Measurement of pulse rate at 5, 15, 30, 45, 60, 90, 120, 150 minutes after entering the ward

**Method of measurement**

Pulse Oximeter

**3**

**Description**

Oxygen saturation

**Timepoint**

Measurement of Oxygen saturation at 5, 15, 30, 45, 60, 90, 120, 150 minutes after entering the ward

**Method of measurement**

Pulse Oximeter

**4**

**Description**

Extubation time

**Timepoint**

The duration of extubation from the time of admission to the Open Heart Intensive Care Unit

**Method of measurement**

Questionnaire

**5**

**Description**

Length of stay in the Unit

**Timepoint**

The duration of the stay in the Intensive Care Unit of the Open Heart surgery after the operation

**Method of measurement**

Questionnaire

**6**

**Description**

Length of hospitalization

**Timepoint**

The duration of the stay in the hospital

**Method of measurement**

Questionnaire

**7**

**Description**

Ramsay Score

**Timepoint**

Measurement of Ramsay score at 5, 15, 30, 45, 60, 90, 120, 150 minutes after admission to the unit

**Method of measurement**

Questionnaire

**8**

**Description**

Mortality

**Timepoint**

Measurement of the number of mortality events in the study population

**Method of measurement**

Questionnaire

**9**

**Description**

Age

**Timepoint**

Registration of patient age

**Method of measurement**

Questionnaire

**10**

**Description**

Sex

**Timepoint**

Registration of patient sex

**Method of measurement**

Questionnaire

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**

First intervention group: (P) that we infuse 10 cc per hour (10 cc/hr) for 4 to 6 hours from a vial of propofol 10% (manufactured by B. Braun, Germany).

**Category**

Treatment - Drugs

**2**

**Description**

Second intervention group: (D) In the Dexmedetomidine group, the syringe pump is filled to a volume of 50 cc and Dexmedetomidine is infused at a dose of 20 µ/hour (manufactured by Elixir Lorestan, Iran) for 4 to 6 hours.

**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Amir Al Mo'menin Hospital

**Full name of responsible person**

Alireza Kamali

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## Sponsors / Funding sources

**1**

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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**
Arak 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**
Arak University of Medical Sciences

**Full name of responsible person**
Taha Rafiei

**Position**
Student of medicine

**Latest degree**
A Level or less

**Other areas of specialty/work**
General Practitioner

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## Person responsible for scientific inquiries

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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**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is 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**

Yes - There is a plan to make this available

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Data will be shared after study completion in accordance with ethical considerations

**When the data will become available and for how long**

Upon completion of the study

**To whom data/document is available**

The public is allowed access

**Under which criteria data/document could be used**

For scientific, research and therapeutic purposes

**From where data/document is obtainable**

first author

**What processes are involved for a request to access data/document**

By mentioning the reference of the study

**Comments**