

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Comparison effect of Midazolam and Dexmedtomidin , on hemodynamic changes during surgery and post operative complication in the surgery of Permcath implantation

#### Protocol summary

##### Study aim

Comparison effect of Midazolam and Dexmedmotidine on hemodynamic changes in patients undergoing Premcath implantation

##### Design

In this double blind randomized clinical trial study ,70 patents candidate for permcath implantation will be selected and randomly divided in to two group of 35 by Random allocation software. In the first group, 0.2 mg / kg / h of Midazolam and in the second group, 0.1 mg / kg / h, Doxedetomidine is injected immediately after induction of anesthesia. Hemodynamic characteristics and postoperative complications, including nausea and vomiting, and severity of pain in patients will be recorded.

##### Settings and conduct

This double blind clinical trial study will be conducted at Al-Zahra hospital in 2019 in Isfahan.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range 18-65 years; (American Society of Anesthesiologists)ASA = 2 and 3; willingness to participate in the study Non Inclusion criteria: receiving drugs that affect hemodynamic status; receiving anticoagulant drugs

##### Intervention groups

Intervention group 1: Injection of 0.2 mg / kg /hour of Midazolam Intervention group 2: Injection of 0.1 ug / kg Doxedetomidine during 10 minutes immediately after induction of anesthesia.

##### Main outcome variables

Systolic blood pressure, diastolic blood pressure, heart rate, SPO2, postoperative pain, postoperative nausea and vomiting

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130311012782N35**

Registration date: **2019-09-10, 1398/06/19**

Registration timing: **prospective**

Last update: **2019-09-10, 1398/06/19**

Update count: **0**

##### Registration date

2019-09-10, 1398/06/19

##### Registrant information

##### Name

Ali Mehrabi kushki

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3629 1510

##### Email address

mehrabi@mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-09-22, 1398/06/31

##### Expected recruitment end date

2020-03-18, 1398/12/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison effect of Midazolam and Dexmedetomidin , on hemodynamic changes during surgery and post operative complication in the surgery of Permcath implantation

### Public title

Comparison of the effect of two drugs Midazolam and Dexmedetomidine on vital signs and postoperative complications

### Purpose

Prevention

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Age range of 65-18 years old American Society of Anesthesiologists (ASA) score of II and III Patient agrees to participate in the study

#### Exclusion criteria:

Receiving drugs that affect hemodynamic status  
Receiving Anticoagulant drugs

### Age

From **18 years** old to **65 years** old

### Gender

Both

### Phase

1

### Groups that have been masked

- Participant
- Investigator

### Sample size

Target sample size: **70**

### Randomization (investigator's opinion)

Randomized

### Randomization description

In this study, 70 patients with inclusion criteria will be selected and randomly allocated to two groups of 35 by Randomization software.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

Patients and researcher will be unaware of the allocation of patients to the groups. The drugs were prepared by one of the operating room personnel not included in the study in the same and encoded syringes and provided to the researcher for injection.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Medical Ethics Committee of Isfahan University of

Medical Sciences

#### Street address

Isfahan University of Medical Sciences, Hezarjerib street

#### City

Isfahan

#### Province

Isfahan

#### Postal code

8174673461

#### Approval date

2018-09-20, 1397/06/29

#### Ethics committee reference number

IR.MUI.REC.1396.3.784

## Health conditions studied

### 1

#### Description of health condition studied

postoperative complications

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Blood Pressure

#### Timepoint

In every 10 minutes during surgery and recovery

#### Method of measurement

Pulse oximetry, Observation

### 2

#### Description

Heart Rate

#### Timepoint

In every 10 minutes during surgery and recovery

#### Method of measurement

Pulse oximetry

### 3

#### Description

Blood Oxygen Saturation

#### Timepoint

In every 10 minutes during surgery and recovery

#### Method of measurement

Pulse oximetry

### 4

#### Description

nausea

#### Timepoint

During stay of patients in recovery

#### Method of measurement

Observation

## 5

### Description

Vomitting

### Timepoint

During stay of patients in recovery

### Method of measurement

Observation

## Secondary outcomes

### 1

#### Description

Hemodynamic disorder

#### Timepoint

Every 10 minutes during surgery and recovery

#### Method of measurement

pulse oximetry

## Intervention groups

### 1

#### Description

Intervention group: group of receive 0.1 micgr/kg intravenously Dexmedetomidine made by Exire company, during 10 minutes immediately after induction

#### Category

Treatment - Other

### 2

#### Description

Intervention group: group of receive 0.2 mg/kg intravenously Midazolam made by Exire company, during 10 minutes immediately after induction

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Alzahra hospital

##### Full name of responsible person

Sareh Sadat Shahidi

##### Street address

Soffeh Street

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

##### Phone

+98 31 3356 3466

##### Email

Shsare40@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Shaghayegh Haghjoo

##### Street address

Hezar Jarib

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

##### Phone

+98 31 3792 3070

##### Email

Haghjoo@med.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

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

Esfahan University of Medical Sciences

##### Full name of responsible person

Seyed Taghi Hashemi

##### Position

Assistant Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Anesthesiology

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Soffeh Street

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##### Province

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+98 31 3669 2174

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Seyed Taghi Hashemi

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Ali Mehrabi Koushki

**Position**

Statistical Consultant

**Latest degree**

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**Other areas of specialty/work**

Epidemiology

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Isfahan

**Province**

Isfahan

**Postal code**

8434193474

**Phone**

+98 31 3356 3466

**Email**

al.mehrabi@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no program to publish

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available