

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

Study aim

Comparison effect of Midazolam and Dexmedetomidine on hemodynamic changes in patients undergoing Permcath implantation

Design

In this double blind randomized clinical trial study ,70 patients 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, Dexmedetomidine 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 Dexmedetomidine 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

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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		Medical Sciences
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		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
		<u>1</u>
		Description of health condition studied postoperative complications ICD-10 code ICD-10 code description
		Primary outcomes
		<u>1</u>
		Description Blood Pressure Timepoint In every 10 minutes during surgery and recovery Method of measurement Pulse oximetry, Observation
		<u>2</u>
		Description Heart Rate Timepoint In every 10 minutes during surgery and recovery Method of measurement Pulse oximetry
		<u>3</u>
		Description Blood Oxygen Saturation Timepoint In every 10 minutes during surgery and recovery Method of measurement Pulse oximetry
		<u>4</u>
		Description nausea Timepoint During stay of patients in recovery Method of measurement Observation
Secondary Ids		
empty		
Ethics committees		
<u>1</u>		
Ethics committee		
Name of ethics committee		Medical Ethics Committee of Isfahan University of

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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

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Soffeh Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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

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

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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