

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Evaluation and comparison of hemodynamic indices during head holding pinning in neurosurgery procedures in two groups receiving Dexmedetomidine and Midazolam (Isfahan, 1397)

Protocol summary

Study aim

The aim of this study was to determine and compare the hemodynamic parameters (systolic and diastolic blood pressure, mean blood pressure and heart rate) during the preservation of the head holder pinning in neurosurgery operations in the two groups receiving midazolam and doxedetomidine.

Design

This clinical trial is randomized, without any control group, with parallel and double-blind groups.

Settings and conduct

Participants of elective neurosurgical patients are selected after evaluating entry and exit criteria and are randomly assigned to receive midazolam or doxedetomidine. Hemodynamic indices are recorded at the time before, 1, 2, and 3 minutes after the preservation of the head holder pinning.

Participants/Inclusion and exclusion criteria

Age between 20 and 70 years, insensitivity to anesthetic drugs, no antihypertensive drug

Intervention groups

First, all patients are anesthetized with fentanyl and atracurium and propofol. To maintain anesthesia, members of the first group (doxedetomidine) use doxedetomidine at a dose of 1 microgram per kg of body weight per hour, and for the anesthetic maintenance, members of the second group (midazolam) receive 0.6 mg / kg of midazolam The body weight is used per hour. Hemodynamic indices are recorded in a period of time.

Main outcome variables

Systolic and diastolic blood pressure, mean blood pressure and heart rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110528006617N3**

Registration date: **2019-05-06, 1398/02/16**

Registration timing: **retrospective**

Last update: **2019-05-06, 1398/02/16**

Update count: **0**

Registration date

2019-05-06, 1398/02/16

Registrant information

Name

Mehrdad Masoudifar

Name of organization / entity

Esfahan University of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

2018-08-23, 1397/06/01

Actual recruitment end date

2019-03-20, 1397/12/29

Trial completion date

2019-03-20, 1397/12/29

Scientific title

Evaluation and comparison of hemodynamic indices

during head holding pinning in neurosurgery procedures in two groups receiving Dexmedetomidine and Midazolam (Isfahan, 1397)

Public title

The Effect of Dexmedetomidine and Midazolam on Hemodynamic Indices During Anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 20 and 70 years Patients who consent to the informed consent to participate in the study.

Exclusion criteria:

Patients who are not allergic to anesthetic drugs. Patients who do not take anti hypertensive drugs to control their blood pressure. Patients who do not receive the Nimodipin drug due to hemorrhage of the subarachnoid.

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **70**

Actual sample size reached: **63**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals selected in this trial are sequentially divided into two groups of D and M by randomized block method. Group M received Midazolam and the D group received Dexmedetomidine during anesthesia.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patient information is hidden by the operating room nurse and injectable drugs are also provided to the physician in similar syringes by an anesthetic technician, while the physician will not have any knowledge concerning the substance in the syringe. In addition, the participants will not be informed about the injectable drugs in each syringe and the names of the operating room personnel.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave

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Isfahan

Postal code

7346181746

Approval date

2017-12-20, 1396/09/29

Ethics committee reference number

IR.MUI.REC.1396.3.979

Health conditions studied

1

Description of health condition studied

General Anesthesia

ICD-10 code

T88.5

ICD-10 code description

Other complications of anesthesia

Primary outcomes

1

Description

Systolic blood pressure

Timepoint

Before intervention and 1 , 2 , 3 min after intervention

Method of measurement

mm-hg, sphygmomanometer

2

Description

Diastolic blood pressure

Timepoint

Before intervention and 1 , 2 , 3 min after intervention

Method of measurement

mm-hg, sphygmomanometer

3

Description

Mean arterial pressure

Timepoint

Before intervention and 1 , 2 , 3 min after intervention

Method of measurement

mm-hg, sphygmomanometer

4

Description

Heart rate

Timepoint

Before intervention and 1 , 2 , 3 min after intervention

Method of measurement

ECG monitor

Secondary outcomes

1

Description

Hypotension

Timepoint

Before intervention and 1 , 2 , 3 min after intervention

Method of measurement

mm-Hg, sphygmomanometer

2

Description

Hypertension

Timepoint

Before intervention and 1 , 2 , 3 min after intervention

Method of measurement

mm-Hg, sphygmomanometer

3

Description

Tachycardia

Timepoint

Before intervention and 1 , 2 , 3 min after intervention

Method of measurement

ECG monitor

4

Description

Bradycardia

Timepoint

Before intervention and 1 , 2 , 3 min after intervention

Method of measurement

ECG monitor

Intervention groups

1

Description

The first intervention group(Dexmedetomidine): Initially, for primary anesthetic, patients receive 2 mg / kg of propofol and 0.5 microgram per kilogram of atherocorum and fentanyl is injected at 3 micrograms per kg of body weight.To maintain anesthesia, they are given a dose of 1mg per kg body weight / hour of doses of dexmedetomidine.

Category

Treatment - Drugs

2

Description

The second intervention group (midazolam): Initially, for primary anesthetic, patients receive 2 mg / kg of propofol and 0.5 microgram per kilogram of atherocorum and fentanyl is injected at 3 micrograms per kg of body weight. To maintain anesthesia, they use Midazolam infusion at a dose of 0.6 mg / kg body weight per hour.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Saint Zahra hospital

Full name of responsible person

Mehrdad Masoudifar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

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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

Mehrdad Masoudifar

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Latest degree

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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