Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 doxedmodyntidine.

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
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Mehrdad Masoudifar
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Esfahan University of medical sciences
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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 subaracnoide.
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
City
Isfahan
Province
Isfehan
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 bllod 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
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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
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Anesthesiology
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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