

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Comparison of the effects of midazolam and dexmedetomidine on sedation levels, hemodynamics and complications in patients under brain stereotaxic surgery

Protocol summary

Study aim

Comparison of the effects of midazolam and dexmedetomidine on sedation levels, hemodynamics and complications in patients under brain stereotaxic surgery

Design

This study is a clinical trial with a control group ,parallel group, double blind, randomized, and sample size of 64 patients.

Settings and conduct

This study was a double-blind clinical trial that was performed on 64 patients undergoing stereotaxic surgery that referred to university hospitals of Isfahan University of Medical Sciences (Al-Zahra and Kashani). Patients in this study were randomly divided into two groups of 32 patients, one of them was sedated with midazolam, and the other group was sedated with dexmedetomidine. The blindness of this study was that patients and anesthetic technicians did not know any type of drug that was injected. Patients in the first group received midazolam at a dose of 1 mg/kg, and the second group received intravenous dose of 1 mcg /kg/min of dexmedetomidine.

Participants/Inclusion and exclusion criteria

inclusion criteria: 1)patients candidates brain stereotaxic surgery 2)age between 18 and 60 3)No history of allergic reaction to both midazolam and dexmedetomidin
exclusion criteria: 1)any change in anesthesia or surgery plan due to any complication 2)patient expiration during surgery

Intervention groups

Patients in this study were randomly divided into two groups of 32 patients, one of them was sedated with midazolam, and the other group was sedated with dexmedetomidine.

Main outcome variables

Hemodynamic parameters including systolic and diastolic blood pressure, heart rate and respiratory rate at preoperative time, 1, 3, 5, 10 and 20 minutes during

surgery, degree of sedation, patient and surgeon satisfaction, recovery time and complications of surgery including bleeding, low blood oxygen saturation and respiratory apnea was measured.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160307026950N12**

Registration date: **2019-06-06, 1398/03/16**

Registration timing: **retrospective**

Last update: **2019-06-06, 1398/03/16**

Update count: **0**

Registration date

2019-06-06, 1398/03/16

Registrant information

Name

Behzad Nazemroaya

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3212 3543

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behzad_nazem@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of midazolam and dexmedetomidine on sedation levels, hemodynamics and complications in patients under brain stereotaxic surgery

Public title

The effects of midazolam and dexmedetomidine in patients under stereotaxic surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

patients candidates brain stereotaxic surgery age between 18 and 60 No history of allergic reaction to both midazolam and dexmedetomidin

Exclusion criteria:

any change in anesthesia or surgery plan due to any complication patient expiration during surgery

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

patients randomly assigned to two different groups A and B with Random Allocation computer software

Blinding (investigator's opinion)

Double blinded

Blinding description

patients and anesthetic technician did not know about administering drugs

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

Hezarjarib street

City

isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2019-03-16, 1397/12/25

Ethics committee reference number

IR.MUI.MED.REC.1397.350

Health conditions studied**1****Description of health condition studied**

respiratory apnea

ICD-10 code

R06.81

ICD-10 code description

Apnea, not elsewhere classified

2**Description of health condition studied**

systolic and diastolic blood pressure

ICD-10 code

I95.2

ICD-10 code description

Hypotension due to drugs

3**Description of health condition studied**

heart rate

ICD-10 code

R00.1

ICD-10 code description

Bradycardia, unspecified

4**Description of health condition studied**

drug sedation level

ICD-10 code

Y47

ICD-10 code description

Sedatives, hypnotics and antianxiety drugs

5**Description of health condition studied**

bleeding

ICD-10 code

T81.0

ICD-10 code description

Haemorrhage and haematoma complicating a procedure, not elsewhere classified

6

Description of health condition studied

oxygen saturation level

ICD-10 code

R09.0

ICD-10 code description

Asphyxia and hypoxemia

Primary outcomes

1

Description

systolic and diastolic blood pressure

Timepoint

preoperative periods, 1, 3, 5, 10 and 20 minutes during surgery

Method of measurement

Non-invasive barometer

2

Description

heart rate

Timepoint

preoperative periods, 1, 3, 5, 10 and 20 minutes during surgery

Method of measurement

pulse oximetry device

3

Description

respiratory rate

Timepoint

preoperative periods, 1, 3, 5, 10 and 20 minutes during surgery

Method of measurement

Count in minute

4

Description

drug sedation level

Timepoint

after end of surgery

Method of measurement

Ramsay sedation scale

5

Description

patient satisfaction

Timepoint

after end of surgery

Method of measurement

Visual Analogue Scale

6

Description

surgeon satisfaction

Timepoint

after end of surgery

Method of measurement

Iowa Satisfaction with Anesthesia Scale

7

Description

recovery time

Timepoint

From the moment of finishing surgery to full recovery time

Method of measurement

In minute using a chronometer

8

Description

bleeding

Timepoint

after end of surgery

Method of measurement

Bleeding above 50 cc

9

Description

low blood oxygen saturation

Timepoint

during surgery

Method of measurement

The drop in oxygen saturation below 90% by pulse oximeter

10

Description

respiratory apnea

Timepoint

during surgery

Method of measurement

Respiratory arrest for more than 8 seconds measured by chronometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group A: Initially, personal consent is obtained from the patients. Then the patient is placed on the operating bed and standard monitoring devices including pulse oximetry, capnography, and electrocardiogram are attached. Patients in this group received midazolam at a dose of 1 mg/kg IV bolus.

Category

Treatment - Drugs

2

Description

Intervention group B: Initially, personal consent is obtained from the patients. Then the patient is placed on the operating bed and standard monitoring devices including pulse oximetry, capnography, and electrocardiogram are attached. The second group received intravenous dose of 1 mcg/kg/min of dexmedetomidine.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahara hospital

Full name of responsible person

Behzad Nazemroaya

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Soffeh boulevard, Shahid Kesari highway

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8174675731

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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

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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

mehdi khademi

Position

medical student / intern

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Dr. Behzad Nazemroaya

Position

Assistant Professor/Faculty

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Specialist

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Sharing plan

Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

mehdi khademi

Position

medical student / intern

Latest degree

Medical doctor

Other areas of specialty/work

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Province

Lorestan

Postal code

6818795459

Phone

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