

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Comparison effect of fentanyl and dexmedtomidine on hemodynamic changes during stereotaxic surgeries

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 ;heart rate;o2 saturation) during the steriotaxic surgeries in two groups of recieving dexmedtomidine and fentanyl.

Design

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

Settings and conduct

This study was performed in Al-Zahra Medical Center in Isfahan.Participants were selected from elective patients with stereotaxic surgery after evaluating the inclusion and exclusion criteria and randomly and double blindly(patients and physician) were placed in the group receiving fentanyl or dexmedetomidine. Hemodynamic parameters were measured before and after every 30 minutes after anesthesia and during recovery. The anesthesia technician provides the drugs to the physician in similar syringes and the anesthesiologist and patients are informed of the groups and names of the drugs. Do not have.

Participants/Inclusion and exclusion criteria

Inclusion criteria :Age between 18 and 65 years old; Patient with American Society of Anesthesiology physical status class 1,2 (ASA I,II). Non- inclusion criteria :patients recieve anticoagulant drugs ; patients recieve drugs affect on hemodynamic status;patients with bradycardia and heart block

Intervention groups

Intervention group 1: group A(patients recieve fentanyl). they receive 2 microgram per kilogram of body weight fentanyl. Intervention group 2 : group B (patients recieve dexmedtomidine) they receive loading dose 1 microgram per kilogram of body weight in 10 minutes then maintenance dose 0.5 microgram per kilogram of body weight per hour dexmedtomidine .

Main outcome variables

Systolic blood pressure; diastolic blood pressure; mean

blood pressure; heart rate; saturation of o2

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110528006617N5**

Registration date: **2021-01-30, 1399/11/11**

Registration timing: **retrospective**

Last update: **2021-01-30, 1399/11/11**

Update count: **0**

Registration date

2021-01-30, 1399/11/11

Registrant information

Name

Mehrdad Masoudifar

Name of organization / entity

Esfahan University of medical sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effect of fentanyl and dexmedetomidine on hemodynamic changes during stereotaxic surgeries

Public title

The effect of dexmedetomidine and fentanyl on hemodynamic indices in Stereotaxic surgeries.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 18-65 years old Patients who consent to the informed consent to participate in the study. Patient with american society of anesthesiology physical status class 1,2(ASA I,II)

Exclusion criteria:

Patients who have bradycardia and heart block. Patients who have anticoagulant drugs. Patients who have drugs affect on hemodynamic status.

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Random function "Random Number Generation " of Excel software based on patient file number will be used for randomization. Patients file number were entered into Excel program and patients were divided into case and control groups based on the random button. In total, there were two groups of 68 people. In this case, the file number is entered in Excel program, then a random number is selected from the data analysis command. This study has 2 groups that can be numbered from 1 to 2, respectively. We also want 34 people in each group. As a result, sequences 1 to 2 should be repeated 34 times each time. It is clear that the repetition of each number occurs once in each group, so select 1 for repeating each number and 34 for repeating the sequence. In this way, 68 units will be produced

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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Province

Isfahan

Postal code

8174673461

Approval date

2017-09-27, 1396/07/05

Ethics committee reference number

IR.MUI.REC.1398.122

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 30,60,90,120 minutes after intervention and recovery time

Method of measurement

Mm-hg, sphygmomanometer

2**Description**

Diastolic blood pressure

Timepoint

Before intervention and 30,60,90,120 minutes after

intervention and recovery time

Method of measurement

Mm-hg, sphygmomanometer

3

Description

Heart rate

Timepoint

Before intervention and 30,60,90,120 minutes after intervention and recovery time

Method of measurement

ECG monitor

4

Description

Mean arterial pressure

Timepoint

Before intervention and 30,60,90,120 minutes after intervention and recovery time

Method of measurement

Mm-hg, sphygmomanometer

5

Description

O2 saturation

Timepoint

Before intervention and 30,60,90,120 minutes after intervention and recovery time

Method of measurement

O2 saturation percentage , pulse oximeter device

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group: 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 are attached. Then 2 microgram per kilogram fentanyl is injected.

Category

Treatment - Drugs

2

Description

The second intervention group: 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 are attached. Then 1 microgram per kilogram dexmedetomidine is infused in 10 minutes and then 0.5 microgram per kilogram per hour dexmedetomidine is infused.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahrah hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

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

Mina Foroughi

Position

Medical student/ Intern

Latest degree

Medical doctor

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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

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