

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparison effect of fentanyl and dexmedtomidin , on hemodynamic changes during craniotomy surgeries

Protocol summary

Study aim

Comparison of the effect of fentanyl and dexmedmotidine on hemodynamic changes in patients undergoing brain tumor surgery

Design

In this study, 70 patients undergoing brain tumor surgery by random allocation method were distributed in two groups of 35, in the first group during the course of the action of doxedmodyntidine and in the second group, fentanyl is injected. The hemodynamic parameters of patients include blood pressure, heart rate and blood oxygen saturation before and after each operation, and then every 30 minutes during recovery and operation. Levels of blood gaz are determined and recorded in patients before and after surgery. Finally, the findings of the two groups are compared.

Settings and conduct

This double-blind clinical trial is conducted in 1398 in Al-Ahra Hospital in Isfahan. 70 patients undergoing brain tumor surgery are divided into two groups of 35, in the first group, dexamethmonidine, and in the second group fentanyl, is injected immediately after induction of anesthesia. The hemodynamic variables and coagulation factors are determined and compared in both groups during operation and recovery.

Participants/Inclusion and exclusion criteria

In this study, patients undergoing bran tumor surgery with an age range of 18-65 years, ASA = 2.3, who did not receive medications that affect hemodynamic status and anticoagulant drugs and who agree to participate in the study, are included in the study.

Intervention groups

In this study, the intervention group was the patients receiving doxedetomidine and the control group receiving fentanyl. In the first group, 0.1 ug /kg doxedetomidine and the second group 5 mg/kg fentanyl are injected immediately after induction of anesthesia.

Main outcome variables

blood pressure, heart rate, O2sat, cuagulation factore

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130311012782N32**

Registration date: **2019-07-15, 1398/04/24**

Registration timing: **prospective**

Last update: **2019-07-15, 1398/04/24**

Update count: **0**

Registration date

2019-07-15, 1398/04/24

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 fentanyl and dexmedetomidin , on hemodynamic changes during craniotomy surgeries

Public title

Comparison of two drugs of dexmedetomidin and fentanyl of blood pressure and heart rate in brain tumor surgeries

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

age range 18-65 years ASA=II.III not receive drugs effect on hemodynamic status not receive anti coagulant drugs agree for participant in the study

Exclusion criteria:

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are distributed in two groups using random allocation software.

Blinding (investigator's opinion)

Double blinded

Blinding description

The method of blindness will be that the patient and the researcher are not aware of the type of drug they receive. The drugs will be provided by a person from the operating room will provided in the same or encoded syringes and receive by researcher for injection

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

Hezar Jarib Street

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8174673461

Approval date

2018-10-16, 1397/07/24

Ethics committee reference number

ir.mui.rec.1396.3.694

Health conditions studied

1

Description of health condition studied

brain tumor

ICD-10 code

C71.0

ICD-10 code description

Malignant neoplasm of cerebrum, except lobes and ventricles

Primary outcomes

1

Description

Blood Pressure

Timepoint

Every 15 minutes during surgery and recovery

Method of measurement

Paloxymetry

Secondary outcomes

1

Description

Coagulation Profile

Timepoint

before and after operation

Method of measurement

Take the blood sample and send it to the lab

Intervention groups

1

Description

Intervention group: receive dexmedetomidin 0.1 ug/kg immediately after induction

Category

Prevention

2

Description

Control group: receive 5 mg/kg fentanyl immediately after induction

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Zohrea Rahimi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name**Grant code / Reference number**

396694

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

Zohrea Rahimi

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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researcher

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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

The information belongs to the government.

Study Protocol

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

Because the information belongs to the government, it is not possible to share it.

When the data will become available and for how long

not applicable

To whom data/document is available

no one

Under which criteria data/document could be used

Medical University license

From where data/document is obtainable

no one

What processes are involved for a request to access data/document

no procedure

Comments