Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of two different doses of dexmedtomidin compared with sufentanil on hemodynamic changes during stereotaxi surgeries

Protocol summary

Study aim
Determination of the Effect of Dexmedetomidine in Comparison with Placebo on Hemodynamic Changes and Patient and Surgeon Satisfaction in Patients with Stereotactic Surgery

Design
Clinical trials are randomized with parallel, blind, randomized groups

Settings and conduct
This study will be conducted at Alzahra Medical Education Center in 1396. The statistical population of the study includes patients undergoing stereotaxic surgery in the center. The medical treatment of both patients in the same group and containing a 10 mg tablet of diazepam the same night before This is a double-blind study. Blind method is that information collector and patients are not aware of the type of drug injected.

Participants/Inclusion and exclusion criteria
Entry requirements: Absence of drugs that affect hemodynamic status and anticoagulants Conditions of non-arrival: the patient's dissatisfaction for entry

Intervention groups
75 inpatient patients are distributed in 3 groups of 25 people. In the first and second groups, we dilute a 200-µg dose of doxedemotvydine in 50cc normal saline. And in the third group, sulfentanil is used at a rate of 0.1-2.0 µg / kg.

Main outcome variables
Improvement and hemodynamic stability; Positive effects on the supply of myocardial oxygen and the demand for oxygen for oxygen and as a result of myocardial protection.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190506043487N1**
Registration date: **2019-06-19, 1398/03/29**
Registration timing: **retrospective**

Last update: **2019-06-19, 1398/03/29**
Update count: **0**

Registration date
2019-06-19, 1398/03/29

Registrant information

Name
negar eghbalifard

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 4523 0321

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-03-20, 1395/12/30

Expected recruitment end date
2018-03-19, 1396/12/28

Actual recruitment start date
2017-10-18, 1396/07/26

Actual recruitment end date
2018-03-19, 1396/12/28

Trial completion date
2018-03-19, 1396/12/28

Scientific title
The effect of two different doses of dexmedtomidin compared with sufentanil on hemodynamic changes during stereotaxi surgeries

Public title

the effect of dexmedmotidine compared with sufentanil on surgeon and patient satisfaction

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age range 15 to 65 years ASA= 2,3 Not receiving drugs that affect hemodynamic status Not receiving drugs that affect hemodynamic status Patient agrees to participate in the study

Exclusion criteria:

receiving drugs that affect hemodynamic status receiving drugs that affect hemodynamic status

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **75**

Actual sample size reached: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method in this study was block randomized, and 75 patients with the conditions of entry were distributed in 3 groups of 25 people.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study was done double blindly and the method of blindness is that the person collecting the information and the patients are not aware of the type of drug injected.

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

۷۳۴۶۱-۸۱۷۴۶

Approval date

2017-10-17, 1396/07/25

Ethics committee reference number

Ir.mui.rec.1396.3.608

Health conditions studied

1

Description of health condition studied

Stereotactic Surgery

ICD-10 code

G94.8*

ICD-10 code description

Other specified disorders of brain in diseases classified elsewhere

Primary outcomes

1

Description

Hemodynamic status of the patient

Timepoint

Before surgery and every 30 minutes during surgery

Method of measurement

Blood pressure in all patients is performed by a person with a calibration device of the same type. Measuring the level of oxygen saturation and heart rate will be done with a pulse oximeter device.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A 200 µg dose of dexmedetomidine in 50 ml of normal saline is diluted. The amount of 1 microgram per kg of plow is infused over a 10 minute period. Then, 0.2 µg / kg is given.

Category

Prevention

2

Description

Intervention group: A 200 µg dose of dexmedetomidine in 50 ml of normal saline is diluted. The amount of 1 microgram per kg of plow is infused over a 10 minute period. Then, 0.5 µg / kg is given.

Category

Prevention

3

Description
Control group: Suffentanil is used at a dose of 0.1-0.2 µg / kg as a booster dose.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Negar Eghbalifard
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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Medical School, Hezar Jarib Ave, Azadi Square
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vcr-office@med.mui.ac.ir
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
Negar Eghbali Fard
Position
Intern
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Person responsible for updating data

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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