

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Effects of dexmedetomidine on Postoperative Shivering and nausea and vomiting in Patients With Opium Addiction After Elective supratentorial Brain tumor Surgeries.

Protocol summary

Study aim

Determining the effect of dexmedetomidine on postoperative shivering, nausea and vomiting in addicted patients.

Design

100 opium addicted patients that are candidated for supratentorial brain tumor surgery and have inclusion criteria will be selected and divided into two groups of control and intervention with block randomized and computer generated randomizid. This study is double blind.

Settings and conduct

Patients with inclusion criteria will be selected in Shohada Tajrish Hospital and after taking consent form and due to dividing to the control and intervention group, placebo and drug will be administered and outcome of them will be recorded in the recovery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: opium addicted; afebrile; without nausea and vomiting before surgery Exclusive criteria: fever; not addiction; history of postoperative nausea and vomiting; history of GI disease

Intervention groups

control group: receiving placebo(Normal Saline)
Intervention group: receiving dexmedetomidine

Main outcome variables

evaluation of postoperative shivering, nausea and vomiting in two group.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201122049464N1**
Registration date: **2020-12-22, 1399/10/02**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-22, 1399/10/02**

Update count: **0**

Registration date

2020-12-22, 1399/10/02

Registrant information

Name

Mona Rajabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2242 7554

Email address

monarajabi1989@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-17, 1399/09/27

Expected recruitment end date

2021-01-16, 1399/10/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of dexmedetomidine on Postoperative Shivering and nausea and vomiting in Patients With Opium Addiction After Elective supratentorial Brain tumor Surgeries.

Public title

Effects of dexmedetomidine on Postoperative Shivering and nausea and vomiting

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

opium addicted with supratentorial Brain afebrile (normotherm)

Exclusion criteria:

not opium addicted febrile with cardiac arrhythmia with history of post operation nausea and vomiting with history of motion sickness with history of GI disease

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

100 opium addicted patients that are candidated for supratentorial brain tumor surgery who have enrollment criteria will be selected. After that we will randomize the patients using a computer-based program with random number generator protocol in two groups of 50 patients (intervention: dexmedetomidine user and control group: placebo user).The site www.calculator.net will be used for this division.According to the instructions of this site, the lower limit of 1 and the upper limit of 100 will be used and according to the software calculations, the numbers will be given to the patients randomly and the numbers 1-50 and the numbers 51-100 will be in the control group or in the intervention group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient who is not responsible for distributing drug, data collecting and analyzing will divide drug and placebo in the boxes without name and will code them by A&B. After that this boxes will be administered to the patients by researcher and trained staff and collected data will be delivered to the analyzer. Also the patients will know about this research and will read consent form but they will not know which groups they are in.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Science

Street address

No.2, Arabi Ave, Velenjak

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2019-05-12, 1398/02/22

Ethics committee reference number

IR.SBMU.MSP.REC.1398.126

Health conditions studied

1

Description of health condition studied

postoperative shivering , nausea and vomiting

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Effect of dexmedetomidine on postoperative shivering , nausea and vomiting.

Timepoint

Upon arrival to the recovery room till minute 150.

Method of measurement

In order to assess research variables such as nausea and vomiting, observation method was applied by the anesthesiologist and a trained nurse during post-operative recovery. Moreover, the Bedside Shivering Assessment Scale (BSAS) was applied to evaluate shivering at the bedside where shivering grades were 2 and 3.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group are the patients who are opium addicted and candidated for supratentaria brain tumor surgery that will be revived drug.(infusion of dexmedetomidine 1 mag/kg/min in 10 minutes and 30 minutes before induction.)

Category

Treatment - Drugs

2**Description**

Control group: This group are the patients who are opium addicted and candicated for supratentorial brain tumor surgery that will be received placebo (infusion of normal salin in 10 minutes and 30 minutes before induction)

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shohadaye Tajrish Hospital

Full name of responsible person

Reza Jalili Khoshnood

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

Yes

Title of funding source

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mona Rajabi

Position

Anesthesiology resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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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

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