

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the effectiveness of propofol-remifentanyl with propofol-dexmedetomidine in reducing pain after awake craniotomy surgery

Protocol summary

Study aim

Comparing the efficacy of propofol-remifentanyl with propofol-dexmedetomidine in reducing pain after awake craniotomy

Design

Phase 3 randomized controlled, open-labeled clinical trial with parallel groups, of 150 patients. For randomization, the random number table provided by graphpad.com is used.

Settings and conduct

This clinical trial will be conducted on eligible patients in the neurosurgery operating room of Sinai Hospital (Tehran University of Medical Sciences). Patients will randomly assigned to one of the two study groups and receive the desired intervention. The intensity of pain, amount of sedation, and total dose of propofol will be evaluated during surgery and recovery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The patient should be a candidate for craniotomy surgery using the sleep-awake-asleep method; The patient does not have a previous craniotomy history; The patient does not have a contraindication for full anesthesia; The patient's age is between 20 and 50 years; The patient does not have a history of allergy to any of the drugs under study. Exclusion criteria: In addition to craniotomy, the patient needs to perform another surgery at the same time; Pregnancy; Breast feeding; The patient has simultaneously heart, renal or liver failure; Severe obesity;

Intervention groups

Intervention group: (dexmedetomidine infusion with a LD of 1 µg/kg/h for 15 minutes and then a MD of 0.2 µg/kg/h) Control group: (propofol 1% infusion with a LD of 250 µg/kg/min for 15 minutes and then a MD of 50 µg/kg/min) + (remifentanyl infusion with a LD of 0.5 µg/kg for 60 seconds and then a MD of 0.1 µg/kg/min)

Main outcome variables

Pain intensity based on the VAS scale

General information

Reason for update

Change of sample size due to: Fewer cases in similar studies in this type of surgery in other countries limitation in patient recruitment

Acronym

IRCT registration information

IRCT registration number: **IRCT20151221025641N5**

Registration date: **2023-03-25, 1402/01/05**

Registration timing: **prospective**

Last update: **2025-03-17, 1403/12/27**

Update count: **2**

Registration date

2023-03-25, 1402/01/05

Registrant information

Name

Parisa Kianpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2660 2854

Email address

pk.pioneer1@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-09, 1402/01/20

Expected recruitment end date

2023-10-12, 1402/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of propofol-remifentanyl with propofol-dexmedetomidine in reducing pain after awake craniotomy surgery

Public title

Comparing the effectiveness of propofol-remifentanyl with propofol-dexmedetomidine in reducing pain after awake craniotomy surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The patient should be a candidate for craniotomy surgery using the sleep-awake-asleep method; The patient does not have a previous craniotomy history; The patient does not have a contraindication for full anesthesia; The patient's age is between 20 and 50 years; The patient does not have a history of allergy to any of the drugs under study.

Exclusion criteria:

In addition to craniotomy, the patient needs to perform another surgery at the same time; Pregnancy; Breast feeding; The patient has simultaneously heart, renal or liver failure; Severe obesity (BMI>30 kg/m2);

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done with the random number table method created by referring to the www.graphpad.com website.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the patient and the person evaluating the VAS scale are unaware of the type of analgesic intervention received during surgery.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Central building, Ghods St., Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1913914435

Approval date

2022-05-11, 1401/02/21

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.147

Health conditions studied

1

Description of health condition studied

Awake craniotomy

ICD-10 code

G94

ICD-10 code description

Other disorders of brain in diseases classified elsewhere

Primary outcomes

1

Description

Pain intensity

Timepoint

On 2,6,12,24,48 hours

Method of measurement

VAS scale

Secondary outcomes

1

Description

Diclofenac suppository dosage required

Timepoint

On 2,6,12,24,48 hours

Method of measurement

Medical record

2

Description

The duration of hospitalization until the patient is able to move

Timepoint

The entire length of hospitalization

Method of measurement

Medical record

3**Description**

Nausea and vomiting

Timepoint

On 2,6,12,24,48 hours

Method of measurement

Patient examination

4**Description**

Vertigo

Timepoint

On 2,6,12,24,48 hours

Method of measurement

Patient examination

Intervention groups**1****Description**

Intervention group: (dexmedetomidine infusion with a LD of 1 µg/kg/h for 15 minutes and then a MD of 0.2 µg/kg/h)

Category

Treatment - Drugs

2**Description**

Control group: (propofol 1% infusion with a LD of 250 µg/kg/min for 15 minutes and then a MD of 50 µg/kg/min) + (remifentanyl infusion with a LD of 0.5 µg/kg for 60 seconds and then a MD of 0.1 µg/kg/min)

Category

Treatment - Drugs

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

Sina hospital

Full name of responsible person

Reza Shariat Moharari

Street address

Sina hospital; Hasan abad Sq., Imam Khomeini Ave.

City

Tehran

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Phone

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Fax**Email**

moharari@sina.tums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

Central building, Ghods Ave., Keshavarz Blvd.

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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

Tehran University of Medical Sciences

Proportion provided by this source

30

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

2**Sponsor****Name of organization / entity**

Anesthesiology, critical care and pain management research center

Full name of responsible person

Farhad Etezadi

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Sina hospital, Hasan abad sq., Imam khomeini Ave.

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Email

accpm.rc.tums@gmail.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Anesthesiology, critical care and pain management research center, Tehran University of Medical Sciences

Proportion provided by this source

70

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

Tehran University of Medical Sciences

Full name of responsible person

Shima Baniasad

Position

Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Reza Shariat Moharari

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shima Baniasad

Position

Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

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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