

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the pregabalin effect on postoperative pain in elective craniotomy

Protocol summary

Study aim

The purpose of this study will be to assess the effect of pregabalin on postoperative pain in elective craniotomy

Design

Clinical trial with two arm parallel groups, randomised trial with double blinded assessment. Study phase will be 2-3.

Settings and conduct

In Urmia Imam Khomeini hospital operating room the patients with craniotomy surgery with general anesthesia will be divided into two parallel groups (50 patients per group). The drug will be administered by the nurse in the ward and at the time of admission, the anesthesiologist will be unaware which patient will be assigned to which group. Drug containers will be identical and only the nurse will know about the contents of each of them, and finally, after collecting information by the resident in training in anesthesiology, the anesthesiology specialist will be informed of the group each patient is assigned to. After surgery pain will be compared with each other.

Participants/Inclusion and exclusion criteria

Inclusion criteria: being at the age of 20 to 60 years old; American Society of Anesthesiologists class I and II; candidate for elective craniotomy. Exclusion criteria: history of congenital mental retardation or mental disorders; pregnancy or breastfeeding; history of systemic malignant tumor; previous treatment using this protocol or participation in another experimental study within the last 30 days; allergy to the drugs used in the study; body mass index greater than 30; drug or alcohol addiction.

Intervention groups

Intervention group1: patients will receive Pregabalin 300 Mg oral tablet, 90 minutes before surgery. Intervention group 2: patients will receive placebo oral tablet, 90 minutes before surgery.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160430027677N23**

Registration date: **2022-10-05, 1401/07/13**

Registration timing: **prospective**

Last update: **2022-10-05, 1401/07/13**

Update count: **0**

Registration date

2022-10-05, 1401/07/13

Registrant information

Name

Shahryar Sane

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 44 3223 4897

Email address

sane.sh@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the pregabalin effect on postoperative pain in elective craniotomy

Public title

The effect of pregabalin on postoperative pain in craniotomy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Being at the age of 20 to 60 years old American Society of Anesthesiologists class I and II Being candidate for elective craniotomy

Exclusion criteria:

History of congenital mental retardation or mental disorders Pregnancy or breastfeeding History of systemic malignant tumor Previous treatment using this protocol or participation in another experimental study within the last 30 days Allergy to the drugs used in the study Body mass index greater than 30 Drug or alcohol addiction

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned into two groups pregabalin 300 mg (group P) and placebo (C) using Random Allocation Software 2.0, and the target codes will be written on a piece of paper and placed in sealed envelopes with sequential allocation.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drug will be administered by the nurse in the ward and at the time of admission, the anesthesiologist will be unaware which patient will be assigned to which group. Drug containers will be identical and only the nurse will know about the contents of each of them, and finally, after collecting information by the resident in training in anesthesiology, the anesthesiology specialist will be informed of the group each patient is assigned to.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

Street address

Orjanse alley, Resalat blvd

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2022-08-30, 1401/06/08

Ethics committee reference number

IR.UMSU.HIMAM.REC.1401.037

Health conditions studied

1

Description of health condition studied

Post craniotomy pain

ICD-10 code

R52.0

ICD-10 code description

Acute pain

Primary outcomes

1

Description

pain

Timepoint

In recovery, 6, 12 and 24 hours after surgery

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Mean Arterial Blood Pressure

Timepoint

In recovery, during Laryngoscopy, 6, 12 and 24 hours after surgery

Method of measurement

None Invasive Blood Pressure

2

Description

Mean pulse Rate

Timepoint

In recovery, during Laryngoscopy, 6, 12 and 24 hours

after surgery
Method of measurement
Electrocardiogram

Intervention groups

- 1**
Description
Intervention group: patients will receive Pregabalin 300 Mg oral tablet, 90 minutes before surgery.
Category
Prevention
- 2**
Description
Control group: patients will receive placebo oral tablet, 90 minutes before surgery.
Category
Placebo
- Recruitment centers**
- 1**
Recruitment center
Name of recruitment center
Operating room, Khomeini Hospital
Full name of responsible person
Shahryar Sane
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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
Oroumia 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
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Shahryar Sane
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Position
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Latest degree
Subspecialist
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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