

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Effect of Gabapentin and Pregabalin premedication versus placebo on pain after septoplasty with and without turbinoplasty: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of Gabapentin and Pregabalin premedication versus placebo on pain after septoplasty with and without turbinoplasty

Design

This is a double-blind randomized clinical trial, phase II, in which 93 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients who are the candidate for septoplasty who will refer to Besat hospital during the study period will be enrolled in the trial

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 65 years; Candidate for septoplasty Exclusion criteria: Concurrent nasal fracture; Need for sinus endoscopy; Addiction

Intervention groups

Intervention group 1: Gabapentin capsule 600 mg (2 capsules 300 mg) single dose 2 hours before surgery
Intervention group 2: Pregabalin capsule 300 mg (2 capsules 150 mg) single dose 2 hours before surgery
Control group: Placebo capsule (2 capsules) single dose 2 hours before surgery

Main outcome variables

Primary outcome: Measuring pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N248**

Registration date: **2018-11-09, 1397/08/18**

Registration timing: **retrospective**

Last update: **2018-11-09, 1397/08/18**

Update count: **0**

Registration date

2018-11-09, 1397/08/18

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0090

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poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Gabapentin and Pregabalin premedication versus placebo on pain after septoplasty with and without turbinoplasty: a double-blind randomized clinical trial

Public title

Effect of Gabapentin and Pregabalin premedication versus placebo on pain after septoplasty with and

without turbinoplasty

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 18 to 65 years; Candidate for septoplasty

Exclusion criteria:

Concurrent nasal fracture; Need for sinus endoscopy;
Addiction

Age

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

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **93**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through the drawing of lots

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double-blind

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2017-04-13, 1396/01/24

Ethics committee reference number

IR.UMSHA.REC.1396.32

Health conditions studied**1****Description of health condition studied**

Deviated nasal septum

ICD-10 code

J34.2

ICD-10 code description

Deviated nasal septum

Primary outcomes**1****Description**

Measuring pain

Timepoint

At 2, 6 and 16 hours after surgery

Method of measurement

Using visual analog scale (VAS)

Secondary outcomes

empty

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

Intervention group 1: Gabapentin capsule 600 mg (2 capsules 300 mg) single dose 2 hours before surgery

Category

Treatment - Drugs

2**Description**

Intervention group 2: Pregabalin capsule 300 mg (2 capsules 150 mg) single dose 2 hours before surgery

Category

Treatment - Drugs

3**Description**

Control group: Placebo capsule (2 capsules) single dose 2 hours before surgery

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Dr Amin Karimian

Street address

Besat Hospital, Shahed Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Dr Amin Karimian

Position

ENT Resident

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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