Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

Phone
+98 81 1838 0090

Email address
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

City
Hamadan

Province
Hamadan

Postal code
6517838695

Phone
+98 81 3364 0030

Email
hqoraishi@gmail.com

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 Fahmideh Ave

City
Hamadan

Province
Hamadan

Postal code
6517838695

Phone
+98 81 3838 0717

Email
info.research@umsha.ac.ir

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

Street address
Besat Hospital, Shahed Square

City
Hamadan

Province
Hamadan

Postal code
6517838695

Phone
+98 81 3364 0030

Email
hqoraishi@gmail.com

Person responsible for scientific 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

Street address
Besat Hospital, Shahed Square

City
Hamadan

Province
Hamadan

Postal code
6517838695

Phone
+98 81 3364 0030

Email
hqoraishi@gmail.com

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
Street address
School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0090
Email
poorolajal@umsha.ac.ir

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