Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of gabapentin on patients restlessness after rhinoplasty

Protocol summary

Study aim

In this study, the effect of prescribing a single dose of 600 mg of gabapentin before surgery on the rate of restlessness at the time of withdrawal from anesthesia in patients undergoing rhinoplasty is investigated.

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2-3 on 120 patients was designed. Block Randomization method was used for randomization

Settings and conduct

This study was performed in Amir Al-Momenin, Namazi, and Kosar hospitals in Shiraz. This trial was performed on 120 patients who were candidates for rhinoplasty in the intervention and control groups. Patients were treated with gabapentin half an hour before surgery according to the defined protocol, and the intervention group received a placebo instead of a drug.

Participants/Inclusion and exclusion criteria

Female candidates for rhinoplasty with ASA class I or II were referred to Amir Al-Momenin Hospital, Namazi or Kosar Hospital in Shiraz. Patients with a diagnosis of dementia, patients with severe preoperative anxiety (yes or no is asked by a doctor), patients with impaired kidney function, patients with a long history (more than 1 month) of anti-anxiety, anti-depressant, neuroleptic drugs, Benzodiazepines, diabetic patients and patients with a history of chronic pain were not included in the study.

Intervention groups

Patients in the intervention group were given two 300 mg (600 mg) gabapentin capsules half an hour before the start of rhinoplasty, which was consumed with a small amount of water. In the control group, two capsules of the same color, shape, and size containing placebo were given half an hour before the start of surgery.

Main outcome variables

Immediately after the operation and during recovery, the patient's restlessness, arterial O2 saturation, arterial blood pressure, heart rate, and expiratory CO2, nausea, and pain were recorded.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200907048652N2**
Registration date: **2021-01-02, 1399/10/13**
Registration timing: **retrospective**

Last update: **2021-01-02, 1399/10/13**
Update count: **0**

Registration date

2021-01-02, 1399/10/13

Registrant information

Name

Hamidreza Hosseinpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3631 1594

Email address

hp_hamid@ymail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-04, 1398/06/13

Expected recruitment end date

2020-09-03, 1399/06/13

Actual recruitment start date

2019-09-04, 1398/06/13

Actual recruitment end date

2020-09-03, 1399/06/13

Trial completion date

2020-09-03, 1399/06/13

Scientific title

Evaluation of the effect of gabapentin on patients restlessness after rhinoplasty

Public title

Evaluation of the effect of gabapentin on patients restlessness after rhinoplasty

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All female candidates for rhinoplasty with ASA class I or II that were referred to Amir Al-Momenin Hospital, Namazi or Kosar Hospital in Shiraz.

Exclusion criteria:

Patients with a diagnosis of dementia, patients with severe preoperative anxiety (yes or no is asked by the physician), patients with impaired kidney function, patients with a long history (more than 1 month) of anti-anxiety drugs, antidepressants, Neuroleptics, benzodiazepines, diabetics and patients with a history of chronic pain were not included in the study.

Age

From **17 years** old to **55 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **120**

Actual sample size reached: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomized according to a pre-prepared list by Block Randomization method in which each of the numbers from 1 to 120 was placed in one of two groups A or B. The mentioned list along with medicine and placebo was kept in the operating room by a person outside the study and after announcing the desired number by the person doing the plan, the medicine or placebo was given to him according to the list so that the person doing it was unaware of the patient group.

Blinding (investigator's opinion)

Double blinded

Blinding description

After explaining the conditions and stages of the study, written consent was obtained from all patients to enter the study and patients were not aware of receiving medication and placebo. Also, the list of patients with medication and placebo was kept in the operating room by a person outside the study, and after announcing the desired number by the person performing the plan, the drug or placebo was given to him according to the list, so that the person performing it was unaware of the patient group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Zand street

City

shiraz

Province

Fars

Postal code

7186611555

Approval date

2019-09-14, 1398/06/23

Ethics committee reference number

IR.SUMS.MED.REC.1398.395

Health conditions studied

1

Description of health condition studied

Rhinoplasty surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

post operative restlessness

Timepoint

Immediately after the operation and then at the time of recovery

Method of measurement

Based on Riker sedation - agitated scale to measure arterial oxygen saturation, arterial blood pressure, heart rate and exhaled CO2

2

Description

pain level

Timepoint

at the time of recovery

Method of measurement
Based on the Numeric Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients were given two 300 mg (600 mg) capsules of gabapentin half an hour before surgery, with a small amount of water.
Category
Prevention

2

Description
Control group: In the control group, two capsules of the same color, shape and size containing placebo were given half an hour before the operation, which was consumed with a small amount of water.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazi Hospital
Full name of responsible person
Hamidreza Hosseinpour
Street address
Zand street
City
shiraz
Province
Fars
Postal code
7193613311
Phone
+98 71 3647 4332
Email
nemazee_inf@sums.ac.ir

2

Recruitment center
Name of recruitment center
Kosar hospital
Full name of responsible person
Hamidreza Hosseinpour
Street address
ghasrodasht
City
shiraz
Province
Fars
Postal code
7187795961
Phone
+98 71 3614 1000
Email
info@kowsar-hospital.ir

3

Recruitment center
Name of recruitment center
Amir-almomenin Hospital
Full name of responsible person
hamidreza
Street address
sadra
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shiraz
Province
Fars
Postal code
7186611555
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Hamidreza Hosseinpour
Street address
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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
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Hamidreza Hosseinpour
Position
Researcher
Latest degree
Medical doctor
Other areas of specialty/work
General Surgery
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
Yes - There is a plan to make this available
Title and more details about the data/document
The results of the study will be published as an article. The study protocol and statistical analysis used in the article will be considered.
When the data will become available and for how long
The information will be published one year after the end of the study and will be available in the sources.
To whom data/document is available
With the sponsor's permission, the information will be available to academic researchers, physicians, and academic institutions.
Under which criteria data/document could be used
Other researchers can use the results of the study in their review and meta-analysis.
From where data/document is obtainable
Hamidreza Hosseinpour - Shiraz, Zand St., Shiraz

University of Medical Sciences, School of Medicine - Department of Surgery

What processes are involved for a request to access data/document

Upon receipt of the application, the scientific officer of the study will respond to the applicant within two weeks, depending on the type of information requested, after coordination with the sponsor.

Comments