Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of a single preoperative dose of300 mg Gabapentin on Postoperative Pain in Rhinoplasty

Protocol summary

Study aim
The Effect of a single preoperative dose of300 mg Gabapentin on Postoperative Pain in Rhinoplasty

Design
This study is double-blinded clinical trial.The study population will be included all patients refer to Imam Khomeini hospital of Kermanshah city.128 eligible patients will be selected conveniently and randomly will be assigned to intervention and control groups.

Settings and conduct
This study, which will be conducted at Imam Khomeini hospital of Kermanshah city is double- blinded one, that participants and clinical carers will be blinded to the study groups, dose of drug and the drug manufacturer.The severity of postoperative pain of both groups is recorded in a checklist.

Participants/Inclusion and exclusion criteria
Inclusion criteria:No history of diabetes, kidney and liver disease; No history of drug abuse Exclusion criteria:Patients who has used Painkiller daily or within 24 hours before surgery ;surgeon; Patients who use antidepressants, anti-epilepsy or antihypertensive drugs

Intervention groups
The intervention group will receive 300 mg of gabapentin capsules one hour before the start of the study.The control group will receive 300 mg of placebo capsules an hour before the start of the study.

Main outcome variables
Intensity of pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130812014333N107**
Registration date: **2018-12-08, 1397/09/17**
Registration timing: **prospective**
Last update: **2018-12-08, 1397/09/17**
Update count: **0**

Registration date
2018-12-08, 1397/09/17

Registrant information

Name
Feizollah Foroughi

Name of organization / entity
kermanshah University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-12-16, 1397/09/25

Expected recruitment end date
2019-03-16, 1397/12/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of a single preoperative dose of300 mg Gabapentin on Postoperative Pain in Rhinoplasty

Public title
The Effect of a single preoperative dose of Gabapentin on Postoperative Pain in Rhinoplasty

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
No history of diabetes, kidney and liver disease No history of drug abuse
Exclusion criteria:
Patients who has used Painkiller daily or within 24 hours before surgery Patients who use antidepressants, anti-epilepsy or antihypertensive drugs

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **128**

Randomization (investigator's opinion)
Randomized

Randomization description
Individual randomization by random number table with code receipt

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, patients and clinical carers will be blinded to the study groups, the dosage of the drug and the manufacturer of the drug.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences

Street address
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Approval date
2017-07-19, 1396/04/28

Ethics committee reference number
ir.kums.rec.1396.186

Health conditions studied

1

Description of health condition studied
post-operative pain after rhinoplasty

ICD-10 code
G89.1

ICD-10 code description
Acute pain, not elsewhere classified

Primary outcomes

1

Description
Intensity of pain

Timepoint
Beginning of study, 2, 4, 6, 12 and 24 hours after surgery

Method of measurement
Visual Analogue Scale(VAS)

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group will receive 300 mg of gabapentin capsules one hour before the start of the study.

Category
Treatment - Drugs

2

Description
The control group will receive 300 mg of placebo capsules an hour before the start of the study.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Khomeini Hospital

Full name of responsible person
Masomeh Foladvand

Street address
Emam Khomeini Hospital, Naghliyeh Street

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Kermanshah

Province
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
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Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti
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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
Kermanshah 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
Kermanshah University of Medical Sciences
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Position
Dentistry student
Latest degree
A Level or less
Other areas of specialty/work
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Person responsible for updating data

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Email

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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

Not applicable

Title and more details about the data/document

The main outcomes of the study will be shared.

When the data will become available and for how long

6 months

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable

To receive the documentation, email send for update manager

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

In a 15-day period, the documents will be sent e-mail

Comments