Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jul 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)

Phone
+98 83 1821 4653

Email address
fforoughi@kums.ac.ir

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
City
Kermanshah
Province
Kermanshah
Postal code

6718743161

Phone
+98 83 3727 9104

Email
hani63210@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Dr. Farid Najafi

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

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Phone
+98 83 3836 0014

Email
fnajafi@kums.ac.ir

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

Full name of responsible person
Masomeh Foladvand

Position
Dentistry student

Latest degree
A Level or less

Other areas of specialty/work
Dentistry

Street address
Faculty of Dentistry,Shariati Street,

City
Kermanshah

Province
Kermanshah

Postal code
6713954658

Phone
+98 83 3729 6591

Email
hani63210@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Dr. Hesamodin Nazari

Position
Faculty Member of Kermanshah University of Medical Sciences

Latest degree
Specialist

Other areas of specialty/work
Oral and Maxillofacial Surgery

Street address
Faculty of Dentistry,Shariati Street,

City
Kermanshah

Province
Kermanshah

Postal code
6713954658

Phone
+98 83 3729 6591

Email
h.nazari@kums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Masomeh Foladvand

Position
Dentistry student

Latest degree
A Level or less

Other areas of specialty/work
Dentistry

Street address
Faculty of Dentistry,Shariati Street,

City
Kermanshah

Province
Kermanshah

Postal code
6713954658

Phone

+98 83 3729 6591
Email
hani63210@yahoo.com

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