Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

Comparing the effect of single doses of preoperative use of Sumatriptan 100 milligram, Pregabalin 75 milligram and Gabapentin 300 milligram on postoperative pain in rhinoplasty

Protocol summary

Study aim
Comparison of effectiveness of preoperative single dose of 100 mg Sumatriptan, 75 mg Pregabalin, 300 mg Gabapentin on pain after rhinoplasty

Design
The clinical trial has three double-blind, randomized, parallel groups

Settings and conduct
90 patients undergoing rhinoplasty are divided randomly into three groups of 30 patients receiving Sumatriptan, Pregabalin and Gabapentin. One hour before surgery, patients will be given the drugs orally. The severity of pain 2, 4, 6, 12, and 24 hours after surgery is measured using Visual Analog Scale (VAS). Data analysis will be done using Stata V14.2 software.

Participants/Inclusion and exclusion criteria
Inclusion criteria: adult volunteers for rhinoplasty with ASA I status Exclusion criteria: Patients with a history of substance, drug or alcohol abuse, patients with renal or hepatic failure, patients with a history of diabetes or patients with diabetes, patients with a history of allergy to any of the drugs used in this study. Patients who take anti-diabetic, antidepressant, antiepileptic or antihypertensive drugs, patients who take painkillers daily or within 24 hours before surgery, as well as patients who are unable to co-operate.

Intervention groups
Volunteers for a rhinoplasty who will enter the trial by signing a written consent, will be randomly divided into three groups: Sumatriptan, Pregabalin and Gabapentin . One hour before the surgery, patients in each group will receive a capsule which contains one of these drugs: 100 mg Sumatriptan, 75 mg Pregabalin, 300 mg Gabapentin.

Main outcome variables
Post-operative pain intensity which would have been acquired, will be compared between the three groups.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140503017537N7**
Registration date: **2020-04-25, 1399/02/06**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-25, 1399/02/06**
Update count: **0**

Registration date
2020-04-25, 1399/02/06

Registrant information

Name
Hesamedin Nazari

Name of organization / entity
Kermanshah University of Medical Sciences , School of Dentistry

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-03-09, 1398/12/19

Expected recruitment end date
2020-05-08, 1399/02/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effect of single doses of preoperative use of Sumatriptan 100 milligram, Pregabalin 75 milligram and Gabapentin 300 milligram on postoperative pain in rhinoplasty

Public title
Comparison of the efficacy of Sumatriptan, Pregabalin and Gabapentin on postoperative pain in rhinoplasty

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Adult individuals volunteering for rhinoplasty with ASA I status.

Exclusion criteria:
Patients with a history of substance abuse, drug abuse or alcohol abuse Patients with kidney or liver failure Patients with diabetes or history of diabetes Patients who are allergic to any of the drugs used in this trial Patients who use antidiabetic medications, antidepressants, anticonvulsants or antihypertensive medications Patients who use painkillers daily or 24 hours before the surgery Patients who are unable to cooperate

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Balanced block randomization

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients are unaware of the group they take part in. Also, the person responsible for evaluating outcomes in the patient has been kept unaware of treatment groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Committee of Ethics in Research, Kermanshah University of Medical Sciences

Street address
No. 26, Valiasr alley, Sadjad blvd.

City
Kermanshah

Province
Kermanshah

Postal code
6718938513

Approval date
2020-02-19, 1398/11/30

Ethics committee reference number
IR.KUMS.REC.1398.1185

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
Severity of postoperative pain

Timepoint
At 2,4,6,12,24 hours after the end of operation

Method of measurement
Using the Visual Analogue Scale(VAS)

Secondary outcomes

1

Description
Nausea and Vomiting

Timepoint
Within 24 hours after surgery

Method of measurement
Yes/No

2

Description
Drowsiness

Timepoint
Within 24 hours after surgery

Method of measurement
Yes/No

Intervention groups

1

Description
Intervention group1: One hour before surgery, patients receive an oral capsule containing 100 mg Sumatriptan with 100 ml of drinking water.
Category
Prevention

2

Description
Intervention group2: One hour before surgery, patients receive an oral capsule containing 75 mg Pregabalin with 100 ml of drinking water.
Category
Prevention

3

Description
Intervention group3: One hour before surgery, patients receive an oral capsule containing 300 mg Gabapentin with 100 ml of drinking water.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Kermanshah Imam Khomeini Hospital
Full name of responsible person
Hamed Nazari
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Farid Najafi
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Vice chancellor for research and technology, Kermanshah University of Medical Sciences, Shahid Beheshti Blvd.
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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
Full name of responsible person
Hamed Nazari
Position
Assistant professor
Latest degree
Specialist
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There are no further information available.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available