

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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+98 918 856 5291

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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

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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

Street address

Imam khomeini Hospital, Naghlieh St.

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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

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Position

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Person responsible for updating data

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Full name of responsible person

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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