

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The Effect of a Single 100 milligram Preoperative Dose of Sumatriptan on Postoperative Pain in Rhinoplasty

Protocol summary

Study aim

The goal of this study is to evaluate the effect of a single 100mg dose of Sumatriptan administered prior to surgery on acute pain after rhinoplasty during 24 hours following the operation

Design

In this study, which is a randomized, double-blinded, placebo-controlled clinical trial, volunteers for rhinoplasty who will enter the trial by signing a written consent, will be randomly divided into two groups, case and control; and pain intensity in both groups will be monitored in 2, 4, 6, 12 and 24 hours after surgery.

Settings and conduct

This is a trial conducted in Imam-Khomeini Hospital at Kermanshah University of Medical Sciences, Kermanshah, Iran. All patients, physicians, surgeons, examiners and operators are blinded to patient allocation to the study groups in this trial.

Participants/Inclusion and exclusion criteria

Inclusion criteria: adult volunteers for rhinoplasty with ASA I status. Exclusion criteria: any history of past or present systemic diseases; hypersensitivity to Triptans, performing any other surgery at the same time as rhinoplasty; patients' unwillingness to stay in the trial at any time.

Intervention groups

volunteers for a rhinoplasty who will enter the trial by signing a written consent, will be randomly divided into two groups, Sumatriptan and placebo. One hour prior to surgery, patients in the case group will receive a 100mg tablets of Sumatriptan, and patients in the control group will receive a placebo tablets.

Main outcome variables

Post-operative pain intensity which would have been acquired, will be compared between the two groups.

General information

Reason for update

end of trial

Acronym

IRCT registration information

IRCT registration number: **IRCT20191127045516N1**

Registration date: **2019-12-12, 1398/09/21**

Registration timing: **prospective**

Last update: **2020-04-08, 1399/01/20**

Update count: **1**

Registration date

2019-12-12, 1398/09/21

Registrant information

Name

hamed Nazari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-07, 1398/10/17

Expected recruitment end date

2020-02-06, 1398/11/17

Actual recruitment start date

2020-01-08, 1398/10/18

Actual recruitment end date

2020-02-14, 1398/11/25

Trial completion date

2020-02-16, 1398/11/27

Scientific title

The Effect of a Single 100 milligram Preoperative Dose of Sumatriptan on Postoperative Pain in Rhinoplasty

Public title

The prophylactic effect of Sumatriptan on pain following plastic nose surgery

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Adult individuals volunteering for rhinoplasty with ASA I status.

Exclusion criteria:

History of previous or present systemic diseases
Hypersensitivity to Triptans Undergoing other surgical operations at the same time of rhinoplasty

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

60 sealed envelopes are prepared, 30 of which contain Sumatriptan 100mg tablets and the other 30 contain placebo tablets. A pharmacist who has no role in this trial, allocates a 4 digit random code to each envelope using the random function on a scientific calculator, and each patient gets one envelope. Therefore, allocation of patients to Sumatriptan or placebo groups is accomplished by simple randomization technique.

Blinding (investigator's opinion)

Double blinded

Blinding description

A pharmacist who has no part in the study, conceals the Sumatriptan and placebo tablets in sealed envelopes and generates a unique random 4 digit number for each envelope. The fact that each 4 digit number shows a Sumatriptan or placebo containing envelope is kept in an allocation chart. The pharmacist keeps the allocation chart sealed till the end of trial. Therefore, random allocation and allocation concealment is achieved for both the patients as well as the operators, examiners, surgeons and clinicians.

Placebo

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

Committee of Ethics in Research, Vice chancellor for research and technology, Kermanshah University of Medical Sciences, Shahid Beheshti Blvd.

City

Kermanshah

Province

Kermanshah

Postal code

6715847167

Approval date

2019-11-25, 1398/09/04

Ethics committee reference number

IR.KUMS.REC.1398.824

Health conditions studied**1****Description of health condition studied**

post-operative pain after rhinoplasty

ICD-10 code

Acute pain

ICD-10 code description

G89.1

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

24 hours after surgery

Method of measurement

yes/no

2

Description

constipation

Timepoint

24 hours after surgery

Method of measurement

yes/no

3

Description

drowsiness

Timepoint

24 hours after surgery

Method of measurement

yes/no

4

Description

difficulty concentrating

Timepoint

24 hours after surgery

Method of measurement

yes/no

5

Description

dry mouth

Timepoint

24 hours after surgery

Method of measurement

yes/no

Intervention groups

1

Description

Intervention group: 1 hour prior to surgery, patients take a 100mg Sumatriptans tablets orally with 100 cc drinking water.

Category

Treatment - Drugs

2

Description

Control group: 1 hour prior to surgery, patients take a placebo tablet orally with 100 cc drinking water.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kermanshah Imam Khomeini Hospital

Full name of responsible person

Hamed Nazari

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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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بلوار شهید بهشتی، دانشگاه علوم پزشکی کرمانشاه، معاونت تحقیقات و فن آوری

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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**Contact****Name of organization / entity**

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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