

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effects of intravenous Paracetamol and Indomethacin suppository for pain relief after septorhinoplasty

Protocol summary

Summary

We designed this prospective, double-blind randomized study to compare the analgesic efficacy of a single- dose of rectal Indomethacin with a single- dose of IV Paracetamol, and those who only receive local infiltration of Lidocaine +Epinephrine in patients undergoing septorhinoplasty. Methods: 75 patients with ASA class I and II undergoing open septorhinoplasty are randomized to 3 groups: group 1 receives 1 gr paracetamol IV in 100 ml normal saline, group 2 rectal indomethacin 100 mg, and group 3 normal saline 100 ml infusion 20 minutes before the end of surgery. A standard anesthetic method is used and all patients receive local infiltration of lidocaine + epinephrine in the operating sites. Postoperative pain is assessed by a visual analogue scale score at 15 and 30 min and at 1, 2, 3, 4, 5, 6, 7, and 8 hours after surgery. IV Morphine boluses is used for supplementary analgesia. Sedation scores and the need for supplementary analgesia and adverse events during the first 8 h after surgery are also recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014041815322N2**

Registration date: **2015-04-20, 1394/01/31**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-04-20, 1394/01/31

Registrant information

Name

Shideh Dabir

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tracheal Diseases Research Center

Expected recruitment start date

2014-04-28, 1393/02/08

Expected recruitment end date

2014-07-23, 1393/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of intravenous Paracetamol and Indomethacin suppository for pain relief after septorhinoplasty

Public title

The effects of intravenous Paracetamol and Indomethacin suppository for treating pain after septorhinoplasty surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: ASA class 1-2, 18-50 years- old patients

Exclusion criteria: drug or alcohol abuse; allergy to study drugs or their constituents; history of renal or hepatic failure or disease; asthma; peptic ulcer; a history of seizures; history of chronic pain.

Age

From **75 years** old to **43 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 75

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**Islamic Azad University of Pharmaceutical Sciences
Branch**Street address**

Shariati street, Yakhchal street

City

Tehran

Postal code**Approval date**

2014-05-21, 1393/02/31

Ethics committee reference number

2867

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

Pain after septorhinoplasty surgery

ICD-10 code

Y83.8

ICD-10 code description

Surgical and other medical procedures as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

Primary outcomes**1****Description**

Postoperative pain scores

Timepoint

15 and 30 min and at 1, 2, 3, 4, 5, 6, 7, and 8 hours after surgery.

Method of measurement

A 0 to 10 visual analogue scale (VAS) score

Secondary outcomes**1****Description**

Supplementary analgesia

Timepoint

During 8 hours study period

Method of measurement

if pain scores are 4 or greater or on patient's demands.

2**Description**

Sedation scores

Timepoint

15 and 30 min, and 1, 2, 3, 4, 5, 6, 7, and 8 hours after surgery.

Method of measurement

Ramsay Sedation Score

3**Description**

Adverse effects

Timepoint

Continuously during 8 hours study period.

Method of measurement

Observation

Intervention groups**1****Description**

Group 1 receives a single dose of 1 gr Paracetamol IV in 100 ml normal saline, 20 minutes before the end of surgery.

Category

Treatment - Drugs

2**Description**

Group 2 receives a single dose of rectal Indomethacin 100 mg, 20 minutes before the end of surgery.

Category

Treatment - Drugs

3**Description**

Group 3 receives Normal saline 100 ml infusion, 20 minutes before the end of surgery.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

National Research Institute of Tuberculosis & Lung Diseases, Masih Daneshvari Hospital

Full name of responsible person

Dr. Tahereh Parsa

Street address

Department of Anesthesiology, Masih Daneshvari Hospital, Darabad, Niavaran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tracheal Diseases Research Center, National Research Institute of Tuberculosis & Lung Diseases, Masi

Full name of responsible person

Dr. Roya Farzanegan

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Grant name

16-11-92

Grant code / Reference number

p/25/29/45095

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tracheal Diseases Research Center, National Research Institute of Tuberculosis & Lung Diseases, Masi

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Azad University of Pharmaceutical Sciences, College of Pharmacy

Full name of responsible person

Miss Yalda Parviz

Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty