

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Comparison of single dose of Paracetamol with single dose of Dexamethasone on postoperative pain of patients undergoing Septoplasty surgery

Protocol summary

Summary

Objective: Comparison of single dose of Paracetamol with single dose of Dexamethasone on postoperative pain of patients undergoing Septoplasty surgery Design: Single blind clinical trial Setting: Patients were divided into three groups randomly: A(Paracetamol) and B(Dexamethasone) and C(Normal saline). Anesthesia was induced in both groups equally using Fentanyl 2 micrograms per kilogram, Midazolam 0.06 milligrams per kilogram, Sodium thiopental 5 milligrams per kilogram and Atracurium 0.5 milligrams per kilogram and was maintained with Propofol infusion (50 microgram per kilogram per minute) and Remifentanyl (0.1 microgram per kilogram per minute). Inclusion criteria: patients with ASA 1 or 2 ; the patients without history of any hepatic and renal disorder; ; without sensitivity to Paracetamol and Corticosteroids; without history of peptic ulcer disease; without history of treatment with Corticosteroids or other immunosuppressive drugs; without history of DM I and II; no drug abuse Exclusion criteria: patients with perioperative hemodynamic instability ; perioperative respiratory distress; perioperative nausea and vomiting or any important adverse effects . Intervention: Group A received Paracetamol 1 gram in 100 milliliter normal saline and because of reduction in analgesic effect of dexamethasone if be diluted in 100 milliliter normal saline and because our study was single blind Group B received 0.1 milligram per kilogram Dexamethasone IV up to 8 milligrams in 10 milliliter normal saline and group C received 100 milliliter Normal saline in 15 minute after induction. Main outcomes: Pain score by VAS at 0 (after extubation), 2, 6, 12 and 24 hours after the end of surgery and Meperidine consumption in 24 hours after surgery and any adverse effects were evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013012712296N1**

Registration date: **2013-02-06, 1391/11/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-02-06, 1391/11/18

Registrant information

Name

Amin Mehrakizadeh

Name of organization / entity

Ahvaz Jondishapour University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 61 1338 3767

Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Ahvaz Jondishapour University of Medical Science

Expected recruitment start date

2011-12-22, 1390/10/01

Expected recruitment end date

2012-12-20, 1391/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of single dose of Paracetamol with single dose of Dexamethasone on postoperative pain of patients undergoing Septoplasty surgery

Public title

The effect of intraoperative administration of IV Paracetamol and Dexamethasone on post operative pain of patient undergoing general anesthesia for Septoplasty surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with ASA 1 or 2 ; the patients without history of any hepatic and renal disorder; without sensitivity to Paracetamol and Corticosteroids; without history of peptic ulcer disease; without history of treatment with Corticosteroids or other immunosuppressive drugs; without history of DM I and II; no drug abuse
Exclusion criteria: patients with perioperative hemodynamic instability ; perioperative respiratory distress; perioperative nausea and vomiting or any important adverse effects .

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **99**

Randomization (investigator's opinion)

Randomized

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

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Ahvaz Jondishapour University of Medical Sciences

Street address

Jondishapour University Center, Golestan Boulevard

City

Ahvaz

Postal code

5555555555

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

ETH-567

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

Postoperative Pain

ICD-10 code

R52.0

ICD-10 code description

Acute Pain

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

Pain score

Timepoint

0 (after extubation), 2, 6, 12 and 24 hours after surgery

Method of measurement

Visual analogue scale

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

Incidence of adverse effects

Timepoint

In 24 hours after surgery

Method of measurement

Asking from patients

2**Description**

Meperidine consumption

Timepoint

In 24 hours after surgery

Method of measurement

milligramms

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

After induction Paracetamol 1 gram in 100 milligrams normal saline in 15 minutes

Category

Treatment - Drugs

2

Description

After induction 0.1 milligram per kilogram up to 8 milligrams Dexamethasone IV in 10 milliliter normal saline in 15 minutes

Category

Treatment - Drugs

3

Description

After induction 100 milliliter normal saline in 15 minutes

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Emam Khomeini General Operation Room

Full name of responsible person

Narges Asadi

Street address

Emam Khomeini Hospital, 20 meter Street

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Ahvaz Jondishapour University of Medical Sciences

Full name of responsible person

Feghi Mostafa

Street address

Vice chancellor for research, University center, Golestan Boulevard

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Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research of Ahvaz Jondishapour University of Medical Sciences

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

Ahvaz Jondishapour University of Medical Sciences

Full name of responsible person

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Position

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Web page address

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