Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Atracorium 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 surger 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

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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 forSeptoplasty 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
City
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
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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