Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Effect of a single dose of Pregabalin before induction of anesthesia on postoperative pain score of septo-rhinoplasty cases ,A double blind RCT

Protocol summary

Summary

Trial is done in Sina hospital, Tehran, Iran. It is a double blind randomized controlled trial using block randomization method as sampling. A single dose of 75 mg of Pregabalin or Placebo intaked by cases or control group two hours before anesthesia induction.We use remifentanil plus isoflurane/propofol in maintenance of anesthesia.Post operative pain is scored by participants during 2 hours of care in post anesthesia care unit by means of Visual Analogue Scale. Also dose of fentanyl as analgesic used in PACU is recorded for every participants according to his/her need. postoperative Pain, Nausea, Vomiting, double vision as side effect and sedation score are evaluated regularly during 24 hours of postoperative period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017043033706N1**
Registration date: **2017-05-22, 1396/03/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-05-22, 1396/03/01

Registrant information

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Name of organization / entity
Tehran University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source
Tehran University of Medical Sciences

Expected recruitment start date
2017-01-20, 1395/11/01

Expected recruitment end date
2017-08-22, 1396/05/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of a single dose of Pregabalin before induction of anesthesia on postoperative pain score of septo-rhinoplasty cases ,A double blind RCT

Public title
Effect of pregabalin on post operative pain of septorhinoplasty

Purpose
Treatment

Inclusion/Exclusion criteria
INCLUSION CRITERIA: Age 18-55 years old ASA Class I-II Candidate for elective Septorhinoplasty, Septoplasty or Rhinoplasty Sign informed consent EXCLUSION CRITERIA: Patients with a history of drug or Alcohol abuse Impaired kidney or liver function Antidiabetic, antidepressant, antiepileptic, antihypertension medication Pregnant or breast feeding patients History of hypersensitivity to any of the drugs used in the study Peptic ulcer, NSAID related dyspepsia History of daily intake of analgesics or intake of any analgesics within 24 hours before septoplasty and inability to cooperate

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

committee of ethics in medical research, Tehran University of Medical Sciences

Street address

Pour Sina street.Tehran University of Medical Sciences.

City

Tehran

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1395.1622

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

R52.9

ICD-10 code description

Pain Unspecified

Primary outcomes

1

Description

Postoperative Pain Score

Timepoint

We Measure Pain at 10 minute pos-extubation, 30 min post-extubation, 60 min post-extubation, 2 hours post-extubation, 6 hours post-extubation and 24 hrs post-extubation.

Method of measurement

Visual Analouge Scale of Pain (VAS)

2

Description

Total fentanyl injected postoperativly

Timepoint

120 minutes post operative

Method of measurement

Based on PACU documents in microgram

3

Description

Total Ibuprofen recived

Timepoint

24 hours post-extubation

Method of measurement

Miligram units based on participants file and answer

Secondary outcomes

1

Description

Extubation time

Timepoint

the time between cessation of all anesthetics and extubation

Method of measurement

Based on minutes, measured by a clock

2

Description

Total remifentanil used during anesthesia

Timepoint

At the time of Extubation

Method of measurement

Measured based on microgram/kg/min

3

Description

Postoperative Agitation

Timepoint

Measured in PACU

Method of measurement

Based on Ramsay Sedation Scale

4

Description

Post¿perative Nausea and Vomiting

Timepoint

During 120 min PACU care; 24 hrs after Extubation

Method of measurement

Obsevation in PACU, Answer of patint after 24 hrs

5

Description
Double vision
Timepoint
During 120 min PACU care; 24 hrs after Extubation
Method of measurement
Answer of patient

Intervention groups

1

Description
A capsule of 75 mg Pregabalin (Lyrica) administered two hours before induction of anesthesia in intervention group
Category
Treatment - Drugs

2

Description
A placebo capsule administered two hrs before induction of anesthesia in control
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital, Tehran University of Medical Sciences
Full name of responsible person
Ali Jalali
Street address
Sina Hospital, 30 Tir street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Shahin Akhondzadeh
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Poursina street, Tehran university of Medical Sciences
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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
Tehran 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

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Person responsible for scientific inquiries

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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