

# 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

###### Name

Ali Jalali

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6312 0000

##### Email address

a.jalali.md@gmail.com

##### 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 post-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 Analogue Scale of Pain (VAS)

**2**

**Description**

Total fentanyl injected postoperatively

**Timepoint**

120 minutes post operative

**Method of measurement**

Based on PACU documents in microgram

**3**

**Description**

Total Ibuprofen received

**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 remifentanyl 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**

Postoperative Nausea and Vomiting

**Timepoint**

During 120 min PACU care; 24 hrs after Extubation

**Method of measurement**

Observation in PACU, Answer of patient 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

#### City

Tehran

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Shahin Akhondzadeh

#### Street address

Poursina street, Tehran university of Medical Sciences

#### City

Tehran

### 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

### Contact

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Ali Jalali

#### Position

Resident of Anesthesiology

#### Other areas of specialty/work

#### Street address

Sina Hospital, 30 Tir street

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#### Postal code

#### Phone

+98 21 6312 0214

#### Fax

#### Email

a.jalali.md@gmail.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Mohamadreza khajavi

#### Position

Professor of Anesthesiology

#### Other areas of specialty/work

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## Person responsible for updating data

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**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Ali Jalali

**Position**

Resident of Anesthesiology

**Other areas of specialty/work****Street address**

Sina Hospital, 30 Tir street

**City**

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**Postal code****Phone**

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**Fax****Email**

a.jalali.md@gmail.com

**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*