Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A comparison of analgesic effect of Intravenous Acetaminophen (Apotel) versus Oxycodone Tablet and oral Acetaminophen codeine in Rhinoplasty and Septoplasty Surgery

Protocol summary

Summary

Purpose: Determine the efficacy of intravenous acetaminophen, Tab acetaminophen codeine,Tab oxycodone in analgesia after Septorhinoplasty surgery. Methods: Multicenter, double-blind clinical trial,on 75 patients, men and women 18 to 40 years, patients must not have any underlying disease, three groups of 25 each, for all patients will infused 1000 mg intravenous acetaminophen over 20 min in the recovery room after surgery. After 6 h of injection of intravenous acetaminophen, 25 patients will take 2 tablets of acetaminophen codeine 300/10 every 6h, 25 patients will take 2 tablets of oxycodone 5 mg every 8 h, and 25 patients will take 1000 mg intravenous acetaminophen every 8 h, until 24 h, The pain of patients will scale with VAS score every 4 h and vital signs monitoring will be every 4 h.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012062410102N1**
Registration date: **2012-12-24, 1391/10/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-12-24, 1391/10/04

Registrant information

Name

Ehsan Bastan hagh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4204 6310

Email address

drbastanhagh@gmail.com

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2011-12-22, 1390/10/01

Expected recruitment end date

2012-06-22, 1391/04/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of analgesic effect of Intravenous Acetaminophen (Apotel) versus Oxycodone Tablet and oral Acetaminophen codeine in Rhinoplasty and Septoplasty Surgery

Public title

Comparing three drugs, apotel, oxycodone and acetaminophen codeine analgesia after nasal surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 18-40 years; Elective patient for septorhinoplasty sergury; Postoperative pain; Anesthesia without complication. exclusion criteria: Any alergic history with acetaminophen; oxycodone, and codeine; Contraindication for opioids; severe pain with high VAS score; Renal disease with Cr >1.5; Liver disease with LFT >1.5 times; Lung disease ; Coagulopathy ; Pregnancy

and lactation; Asthma; Unstable hemodynamic; Anti epileptic agents

Age
From **18 years** old to **40 years** old

Gender
Both

Phase
N/A

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
Tehran University of Medical Sciences

Street address
5th flour, Corner of ghods St, Keshavarz Blv.

City
Tehran

Postal code

Approval date
2012-07-01, 1391/04/11

Ethics committee reference number
130/568/91/د

Health conditions studied

1

Description of health condition studied
control of post operative pain

ICD-10 code
Y45

ICD-10 code description
Analgesics, antipyretics and anti-inflammatory drugs

Primary outcomes

1

Description
pain

Timepoint
every 4 hours

Method of measurement
VAS scaling

Secondary outcomes

1

Description
nausa and vomiting

Timepoint
every 4 hours

Method of measurement
asking

Intervention groups

1

Description
Tab Acetaminophen Codeine 310 mg 2 Tab every 6 hours for 24 hours

Category
Treatment - Drugs

2

Description
Tab oxycodone 5 mg 2 Tab every 8 hours for 24 hours

Category
Treatment - Drugs

3

Description
Amp apotel 1000 mg 1 Amp every 8 hours for 24 hours

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Hazrat Fatemeh Hospital

Full name of responsible person
Ehsan Bastanhagh

Street address
21th St, Yousefabad St.

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Tehran University of Medical Science

Full name of responsible person

Dr. Akbar Fotouhi

Street address

6th floor, Qods St. Keshavarz Blv.

City

Tehran

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 Tehran University of Medical Science

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

Ehsan Bastanhagh

Position

physician/ Resident

Other areas of specialty/work

Street address

4th floor,Rasol hospital, Niayesh St, Satarkhan St.

City

Tehran

Postal code

Phone

+98 21 6435 2326

Fax

Email

e-bastanhagh@razi.tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical science

Full name of responsible person

Mahmoodreza Alebouye

Position

Assistant Prof.

Other areas of specialty/work

Street address

4th floor, Rasool Hospital, Niayesh St. Satarkhan St.

City

Tehran

Postal code

Phone

+98 21 6435 2326

Fax

Email

dr.alebouye@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran Uneversity of Medical science

Full name of responsible person

Ehsan Bastanhagh

Position

Physician/ resident

Other areas of specialty/work

Street address

4th floor, Rasool Hospital< Niayesh St, Satarkhan St.

City

Tehran

Postal code

Phone

+98 21 6435 2326

Fax

Email

e-bastanhagh@razi.tums.ac.irehsanbastanhagh@yahoo.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