

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 be 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 surgery; Postoperative pain; Anesthesia without complication. exclusion criteria: Any allergic 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/ۛ

## 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 Bastanagh

##### 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 Bastanagh

**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-bastanagh@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 University of Medical science

**Full name of responsible person**

Ehsan Bastanagh

**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-  
bastanagh@razi.tums.ac.irehsanbastanagh@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*