Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Comparison of the prophylactic analgesic effects of acetaminophen and celecoxib in patients undergoing rhinoplasty operation

Protocol summary

Summary

Rhinoplastic surgery is one of the most prevalent surgeries and post-surgical pain control is very important. The aim of this study is to compare the prophylactic analgesic effects of acetaminophen and celecoxib in patients undergoing rhinoplastic surgery. In this double blind active controlled clinical trial 70 patients aged 18-40 y/o who candidate for rhinoplasty+ osteotomy and after completion of informed consent form will randomly divided into 2 groups; case group (tab celecoxib 200mg, 30min before operation and every12 hours after first dose till24 hours) and control group (tab acetaminophen 500 mg, 30min before operation and every 6 hours after first dose till 24 hours). Pain severity will be measured immediately before the first dose, 2 hours after surgery and every 6 hours till 24 hours using VAS score (or immediately before drug consumption in concurrency situation). The protocol of general anesthesia will be similar in all patients. History of allergy to medications; unwillingness to participate; severe drugs side effects; underlying disease and alcohol or drug addiction are exclusion criteria. All gathering data will be compared between 2 groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012102111191N1**
Registration date: **2013-01-19, 1391/10/30**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-01-19, 1391/10/30

Registrant information

Name

Atena Esmaeli

Name of organization / entity

Pharmacy School of Shahid Beheshti University of Medical Sciences

Country

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Phone

+98 21886623340

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Shahid Beheshti University of Medical Sciences.

Expected recruitment start date

2012-03-20, 1391/01/01

Expected recruitment end date

2013-03-19, 1391/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the prophylactic analgesic effects of acetaminophen and celecoxib in patients undergoing rhinoplasty operation

Public title

Comparison of the prophylactic analgesic effects of acetaminophen and celecoxib in patients undergoing rhinoplasty operation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: functional class I; completed informed

consent form Exclusion criteria: history of allergy to acetaminophen or sulfonamides; unwillingness to participate in the study; complications of rhinoplastic surgery; severe drugs side effects; current sever illnesses such as: cardiovascular disease, diabetes mellitus type1, obstructive pulmonary disease and asthma, sever HTN, epilepsy, renal or liver dysfunction, analgesic consumption 12 hours before the surgery, alcohol or drug addiction.

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: **70**

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
Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address
Pharmacy School of Shahid Beheshti University of Medical Sciences, Valiasr St, Tehran.

City
Tehran

Postal code

Approval date
2012-02-05, 1390/11/16

Ethics committee reference number
90-11-16

Health conditions studied

1

Description of health condition studied
post surgical pain

ICD-10 code
Z42.0

ICD-10 code description
Follow-up care involving plastic surgery of head and neck

Primary outcomes

1

Description
Pain severity

Timepoint
before operation, 2hours after rhinoplasty, every 6 hour till 24 hours

Method of measurement
Visual Analogue Scale(VAS)

2

Description
Requested analgesic dose

Timepoint
first 24 hours

Method of measurement
mg

Secondary outcomes

1

Description
Surgical site bleeding

Timepoint
first 24 hours

Method of measurement
Observation

Intervention groups

1

Description
Intervention: Tab Celecoxib 200 mg, 30min before operation, every 12 hour in first 24 hours

Category
Treatment - Drugs

2

Description
Control group: Tab Acetaminophen 500 mg, 30 min before operation, every 6 hour in first 24 hours

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Loghman Hakim Hospital

Full name of responsible person
Jamshid Salamzadeh
Street address
Loghman Hakim Hospital, Makhsus Ave, Kamali Ave, South Kargar Ave, Tehran.
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Vice Chancellor for Research of Shahid Beheshti University of Medical Sciences, Valiasr St, Tehran.
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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
Vice Chancellor for Research of Shahid Beheshti 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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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