Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Comparison of Sublingual buprenorphine and intravenous morphine for postoperative analgesic effect hemodynamic changes, nausea & vomiting

Protocol summary

Summary

In this study, we compare sublingual buprenorphine and intravenous morphine for postoperative analgesic effect, hemodynamic changes, nausea, and vomiting. A total of 100 patients, aged 18-60 years old, and in ASA Class I, II, undergoing lower limbs orthopedic surgery, herniorraphy, or varicocelectomy were studied. The patients were randomly assigned to receive sublingual buprenorphine (0.4mg) or IV morphine (6mg) before administration of analgesic after the operation. Vital signs, o2sat, pain severity, nausea & vomiting, itching, respiratory rates, and hemodynamic changes were assessed and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012203305N2**
Registration date: **2011-01-31, 1389/11/11**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-01-31, 1389/11/11

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor Of Research, Babol University Of Medical Sciences

Expected recruitment start date

2010-04-21, 1389/02/01

Expected recruitment end date

2010-12-22, 1389/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Sublingual buprenorphine and intravenous morphine for postoperative analgesic effect hemodynamic changes, nausea & vomiting

Public title

Comparison of Sublingual buprenorphine and intravenous morphine for postoperative analgesic effect hemodynamic changes, nausea & vomiting

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 18-60 years old, ASA Class I, II, candidate for lower limbs orthopedic surgery, herniorraphy, or varicocelectomy Exclusion criteria: History of complications such as: respiratory, cardiovasculer diseases, hypertension, diabetes mellitus, or addiction

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked
No information
Sample size
Target sample size: **100**
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
Babol University Of Medical Sciences
Street address
University Square, Ganjafrooz Avenue, Babol
City
Babol
Postal code
Approval date
2010-04-20, 1389/01/31
Ethics committee reference number
164/30/پ/ژ

Health conditions studied

1

Description of health condition studied
Spinal anesthesia in ASA ClassI, II
ICD-10 code
Other comp
ICD-10 code description
Other complications of anaesthesia

Primary outcomes

1

Description
Postoperative analgesic effect
Timepoint
before intervention untill 12 hours after intervention
Method of measurement
Visual analogue pain score

2

Description
Hemodynamic changes
Timepoint
before intervention untill 12 hours after intervention
Method of measurement
Pulse Oxymeter , Sphigmo manometer

3

Description
Nausea & Vomiting
Timepoint
Before intervention untill 12 hour after intervention
Method of measurement
Visual - questional

Secondary outcomes

1

Description
Oxygen saturation
Timepoint
15, 30, 60 min after procedure, half an hour, before and after 2 and 12 hours
Method of measurement
pulse oximeter

Intervention groups

1

Description
Sublingual buprenorphine 0.4mg as well as 6 ml N/S as placebo
Category
Prevention

2

Description
IV morphine 6mg in 3 min as well as a sublingual tab as placebo
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Babol Beheshti Hospital
Full name of responsible person
Dr Ebrahim Alijanpour
Street address
City
Babol

2

Recruitment center
Name of recruitment center

Babol Yahyanejad Hospital

Full name of responsible person

Dr Ebrahim Alijanpour

Street address

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research, Babol University Of Medical Sciences

Full name of responsible person

Dr Ebrahim Alijanpour

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University Square, Ganjafrooz Avenue, Babol

City

Babol

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, Babol 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

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Email

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