

# 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, herniorrhaphy, or varicocelelectomy 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,  $o_2sat$ , 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

###### Name

Ebrahim Alijanpour

###### Name of organization / entity

Babol University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 1228 0013

###### Email address

dralijanpour@mubabol.ac.ir

##### 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, herniorrhaphy, or varicocelelectomy Exclusion criteria: History of complications such as: respiratory, cardiovascular 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/ز

## 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  
**Street address**  
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**  
Babol University Of Medical Sciences  
**Full name of responsible person**  
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Assistant Professor Of Anesthesiology  
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## Web page address Person responsible for scientific inquiries

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## Person responsible for updating data

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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*