

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Comparison the efficacy of morphine and sublingual buprenorphine in decreasing postoperative pain in orthopedic surgery of the lower limbs

#### Protocol summary

##### Study aim

The aim of this study is to compare Buprenorphine with Morphine in pain relief after the lower limb orthopedic surgeries.

##### Design

In this research, 60 eligible patients candidate for lower limb orthopedic surgery were chosen. They randomly were allocated in two intervention groups of Morphine (n=30) and Buprenorphine (n=30).

##### Settings and conduct

This study was conducted on patients who referred to Ardabil Imam Khomeini hospital. Patients in the morphine group received 20 mg morphine by PCA pump and placebo tablets (similar to buprenorphine pills) and patients in the buprenorphine group received buprenorphine tablets and placebo PCA pump (normal saline). The patients and the nurse prescribing the drugs were not aware of the contents of the pumps and tablets.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria were patients candidate for lower limb orthopedic surgery, ASA class I & II, age between 20-60 years old. Patients with previous hypersensitivity to Buprenorphine and Morphine, History of analgesic use in the past 24 hours, Pregnant and lactating women, Addiction to Narcotic or Alcohol or Benzodiazepines were excluded.

##### Intervention groups

Patients in the first group received 20 mg morphine by PCA pump and placebo tablets (similar to buprenorphine pills), and in the second group received buprenorphine tablets and placebo PCA pump (normal saline).

##### Main outcome variables

The two groups were compared in terms of Postoperative pain, Nausea, Vomiting, and Itching.

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20160802029162N2**

Registration date: **2017-12-20, 1396/09/29**

Registration timing: **retrospective**

Last update: **2017-12-20, 1396/09/29**

Update count: **0**

#### Registration date

2017-12-20, 1396/09/29

#### Registrant information

##### Name

Neda Fathi

##### Name of organization / entity

Ardabil University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 45 3374 7222

##### Email address

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#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2016-09-20, 1395/06/30

#### Expected recruitment end date

2017-09-21, 1396/06/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison the efficacy of morphine and sublingual buprenorphine in decreasing postoperative pain in orthopedic surgery of the lower limbs

**Public title**

Efficacy of morphine and buprenorphine in post-operative pain

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Lower Limb Orthopedic Surgery ASA class I or II age between 20 and 60 years old

**Exclusion criteria:**

Previous hypersensitivity to Buprenorphine Previous hypersensitivity to Morphine History of analgesic use in the past 24 hours Pregnant and lactating women Addiction to Narcotic or Alcohol or Benzodiazepines

**Age**

From **20 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients were allocated randomly to one of the two groups using a computer-generated random number table and sealed envelope technique.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patients in the morphine group received morphine PCA pump and placebo tablets (similar to buprenorphine pills) and patients in the buprenorphine group received buprenorphine tablets and placebo PCA pump (normal saline). The patients and the nurse prescribing the drugs were not aware of the contents of the pumps and tablets.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Ardabil University of Medical Sciences

**Street address**

Daneshgah st. Ardabil Complex University.

**City**

Ardabil

**Province**

Ardabil

**Postal code**

56189-85991

**Approval date**

2016-12-11, 1395/09/21

**Ethics committee reference number**

IR.ARUMS.REC.1395.95

**Health conditions studied****1****Description of health condition studied**

Fractures in lower limbs

**ICD-10 code**

T025

**ICD-10 code description**

Fractures involving multiple regions of both lower limbs

**Primary outcomes****1****Description**

postoperative pain

**Timepoint**

at 1, 8, 16, and 24 hours after surgery

**Method of measurement**

Visual Analogue Scale

**Secondary outcomes****1****Description**

Nausea

**Timepoint**

at 1, 8, 16, and 24 hours after surgery

**Method of measurement**

N/V Score

**2****Description**

Vomiting

**Timepoint**

at 1, 8, 16, and 24 hours after surgery

**Method of measurement**

N/V Score

**3****Description**

Itching

**Timepoint**

at 1, 8, 16, and 24 hours after surgery

**Method of measurement**

asking the patient

## Intervention groups

### 1

#### Description

Intervention group 1: Patients in this group received 20 mg morphine by PCA pump and placebo tablets (similar to buprenorphine pills).

#### Category

Prevention

### 2

#### Description

Intervention group 2: Patients in this group received buprenorphine tablets and placebo PCA pump (normal saline).

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ardabil Imam Khomeini Hospital

##### Full name of responsible person

Dr. Ali Mohammadia Ardi

##### Street address

Imam Khomeini Hospital, Ataee st.

##### City

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##### Province

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ardabil University of Medical Sciences

##### Full name of responsible person

Dr. Shahram Habibzadeh

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Ardabil Complex Univesity, Daneshgah st.

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s.habibzadeh@arums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Ardabil University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Ardabil University of Medical Sciences

##### Full name of responsible person

Saba Esmaeeli

##### Position

Medical student

##### Latest degree

Medical doctor

##### Other areas of specialty/work

General Practitioner

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## Person responsible for scientific inquiries

#### Contact

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##### Full name of responsible person

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##### Position

Anesthesiologist

##### Latest degree

Specialist

##### Other areas of specialty/work

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## Person responsible for updating data

### Contact

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**Position**  
Medical student  
**Latest degree**  
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**Other areas of specialty/work**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

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### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available