

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Comparison of Buprenorphine with Morphine in post-operative pain after orthopedic surgeries.

#### Protocol summary

##### Summary

The aim of this research is to compare Buprenorphine with Morphine to relieve pain after the Orthopedic surgery . All patients are candidated for orthopedic surgery (Closed Reduction)and who are Over 18 years of age , if they are satisfied for the study , could be enrolled into this study . The main exclusion criteria are: previous allergy to Buprenorphine and Morphine; addiction to narcotic , alcohol , benzodiazepines ; history of analgesic use in the past 24 hours . This study included patients referred to the Imam Reza hospital in Mashhad . The sample size in each group (Morphine and Buprenorphine) is 45 . To the patients in the Morphine group, 0.2 mg/kg as intravenous Morphine (maximum ten mg) before induction of anesthesia and in the Buprenorphine group, 4.5 mcg/kg Buprenorphine(maximum one mg) as sublingual , 30 minutes before induction of anesthesia will be given . The two groups are under a same general anesthesia and until 12 hours after surgery, the pain and side effects of drugs (nausea - vomiting - itching - urinary retention) are evaluated.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012101311102N1**

Registration date: **2013-07-24, 1392/05/02**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2013-07-24, 1392/05/02

##### Registrant information

##### Name

Mahmood Khorsand

##### Name of organization / entity

Mashhad University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 1610 9178

##### Email address

khorsandm901@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Research Finance of Mashhad University of Medical Science( Research Manager)

##### Expected recruitment start date

2013-08-20, 1392/05/29

##### Expected recruitment end date

2013-11-20, 1392/08/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of Buprenorphine with Morphine in post-operative pain after orthopedic surgeries.

##### Public title

Comparison of Buprenorphine with Morphine in post-operative pain after orthopedic surgeries.

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: Orthopedic surgery(closed reduction-Pinning); Duration of surgery between thirty minutes to one hundred and twenty minutes; Over 18 years of age; ASA class I,II Exclusion criteria: Previous hypersensitivity to Buprenorphine and Morphine; History of analgesic use in the past 24 hours; Duration of surgery less than thirty

minutes and more than one hundred and twenty minutes; Pregnant and lactating women; Addiction to Narcotic or Alcohol or Benzodiazepines.

#### Age

From **18 years** old to **100 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **90**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Triple blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Mashhad University of Medical Science

##### Street address

Fakori Blvd, Mashhad University of Medical Science

##### City

Mashhad

##### Postal code

#### Approval date

2013-02-12, 1391/11/24

#### Ethics committee reference number

910638

## Health conditions studied

### 1

#### Description of health condition studied

Orthopedic Surgeries

#### ICD-10 code

T02.6

#### ICD-10 code description

Fractures involving multiple regions of upper limb(s) with lower limb(s)

## Primary outcomes

### 1

#### Description

Postoperative pain

#### Timepoint

Entry to recovery-30 minutes later-3hours later-6hours later-12hours later

#### Method of measurement

VAS scale

## Secondary outcomes

### 1

#### Description

Nausea

#### Timepoint

Entry to recovery-30 minutes later-3hours later-6hours later-12hours later

#### Method of measurement

Clinical evaluation and patient complaints

### 2

#### Description

Vomiting

#### Timepoint

Entry to recovery-30 minutes later-3hours later-6hours later-12hours later

#### Method of measurement

Clinical evaluation and patient complaints

### 3

#### Description

Itching

#### Timepoint

Entry to recovery-30 minutes later-3hours later-6hours later-12hours later

#### Method of measurement

Clinical evaluation and patient complaints

### 4

#### Description

urinary retention

#### Timepoint

Entry to recovery-30 minutes later-3hours later-6hours later-12hours later

#### Method of measurement

Clinical evaluation and patient complaints

## Intervention groups

### 1

#### Description

In the Morphine group , 0.2 mg kg as intravenous Morphine (maximum ten mg) is administered before induction of anesthesia.

#### Category

Prevention

## 2

### Description

In Buprenorphine group , 4.5 mcg/ kg Buprenorphine (up to a 1 mg)Prescribed as sublingual , half-hour before induction of anesthesia.

### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Emam Reza hospital

##### Full name of responsible person

Dr. Ghasem Soltani

##### Street address

Emam Reza hospital, anesthesia group

##### City

Mashhad

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences- Deputy for research

##### Full name of responsible person

Dr. Ghasem Soltani

##### Street address

Emam Reza hospital

##### City

Mashhad

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Mashhad University of Medical Sciences- Deputy for research

#### 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

Mashhad University of Medical Science, Emam Reza

hospital

#### Full name of responsible person

Dr. Ghasem Soltani

#### Position

Associate Professor of Anesthesia

#### Other areas of specialty/work

#### Street address

Anesthesia group, Emam Reza hospital

#### City

Mashhad

#### Postal code

#### Phone

+98 51 1802 2711

#### Fax

#### Email

SoltaniGh@mums.ac.ir

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Mashhad University of Medical Science, Emam Reza hospital

#### Full name of responsible person

Dr. Nahid Zirak

#### Position

Associate Professor of Anesthesia

#### Other areas of specialty/work

#### Street address

Anesthesia group; Emam Reza hospital

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ZIRAKN@MUMS.AC.IR

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## Person responsible for updating data

### Contact

#### Name of organization / entity

Mashhad University of Medical Science, Emam Reza hospital

#### Full name of responsible person

Dr. Mahmood Khorsand

#### Position

Resident of anesthesia

#### Other areas of specialty/work

#### Street address

Anesthesia group, Emam Reza hospital

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#### Phone

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#### Fax

#### Email

khorsandm901@mums.ac.ir

**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*