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
ne.fathi@arums.ac.ir

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
Ardabil
Province
Ardabil
Postal code
56189-85991
Phone
+98 45 3325 1401
Email
a.mohammadian@arums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Dr. Shahram Habibzadeh
Street address
Ardabil Complex Univesity, Daneshgah st.
City
Ardabil
Province
Ardabil
Postal code
56189-85991
Phone
+98 45 3352 2247
Email
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
Street address
Imam Khomeini hospital , Ataee St, Ardabil
City
Ardabil
Province
Ardabil
Postal code
56189-85991
Phone
+98 45 3325 1401
Email
SabaEsmaeelimed@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Dr. Ghodrat Akhavan Akbari
Position
Anesthesiologist
Latest degree
Specialist
Other areas of specialty/work
Street address
Fatemi hospital, Imam Khomeini st., Ardabil
City

Ardabil

Province

Ardabil

Postal code

5614733775

Phone

+98 45 3323 4682

Fax

Email

g.akbari@arums.ac.ir

Web page address

Person responsible for updating data

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

Street address

Imam Khomeini hospital , Ataee St, Ardabil

City

Ardabil

Province

Ardabil

Postal code

56189-85991

Phone

+98 45 3325 1401

Email

SabaEsmaeelimed@gmail.com

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