Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of buprenorphine in the control of pain after orthopedic surgery

Protocol summary

Summary

Pain is prevalent after orthopedic surgery and it is necessary to find out a solution to control it. We evaluate the effect of buprenorphine in the control of pain after orthopedic surgery. One of the advantages of this drug is that, it is used sublingual and reduces the request of other analgesics. It has some complication such as nausea and vomiting and headache and vertigo. 186 individuals are randomly selected and divided into 3 groups. Inclusion criteria are age group of 15-65 and ASA class I, II and the patients who are candidate for limb's orthopedic surgery. Exclusion criteria are history of using analgesic and narcotic prior to the surgery; history of chronic lung and heart diseases; history of using Corticosteroids; history of using benzodiazepine. 0.4mg of sublingual buprenorphine, is given to 62 patient's 30 min before operation as A group. 0.4mg of sublingual buprenorphine, was given to 62 patient's, 30 min after operation as B group. 62 patients are taking 25mg pethedine after operation as control group. All 3 groups are identically anesthetised and are controlled each 2 hours to 12 hours and the results are listed in checklist.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108292080N11**
Registration date: **2011-09-29, 1390/07/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-09-29, 1390/07/07

Registrant information

Name

Afsaneh Norouzi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 1313 7474

Email address

norouzi.a@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak university of medical sciences

Expected recruitment start date

2011-04-04, 1390/01/15

Expected recruitment end date

2011-09-08, 1390/06/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of buprenorphine in the control of pain after orthopedic surgery

Public title

The effect of buprenorphine in the control of pain after orthopedic surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: the patient who are candidate for limb's orthopedic surgery and age group of 15-65 and ASA class I,II . Exclusion criteria: history of using analgesic and narcotic prior to the surgery; history of chronic lung and heart diseases; history of using Corticosteroids; history of using benzodiazepine.

Age
From **15 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **186**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Arak university of medical sciences
Street address
Alamol hoda street
City
Arak
Postal code
Approval date
2011-03-15, 1389/12/24
Ethics committee reference number
89-103-5

Health conditions studied

1

Description of health condition studied
orthopedic surgery
ICD-10 code
T01.2 ، T0
ICD-10 code description
Open wounds involving multiple body regions

2

Description of health condition studied
orthopedic surgery
ICD-10 code
T02.2 ، T0
ICD-10 code description
Fractures involving multiple body regions

3

Description of health condition studied
orthopedic surgery
ICD-10 code
T03.2 ، T0
ICD-10 code description
Dislocations, sprains and strains involving multiple body regions

Primary outcomes

1

Description
pain
Timepoint
every 2 hours
Method of measurement
VAS and check list and physical examination

Secondary outcomes

1

Description
nausea and vomitting
Timepoint
every 2 hours
Method of measurement
check list and physical examination

Intervention groups

1

Description
First group: 0.4 mg sub lingual buprenorphine, 30 min before operation
Category
Prevention

2

Description
Second group: 0.4 mg sub lingual buprenorphine, 30 min after operation
Category
Prevention

3

Description
Control group: 25 mg pethedine after operation
Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Valieasr hospital
Full name of responsible person
Dr. Afsaneh Norouzi
Street address
Valiasr hospital, Emam khomeyni street
City
Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak university of medical sciences
Full name of responsible person
Dr.Changizi Ashtiyani
Street address
Alamol hoda street
City
Arak
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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
Arak university of medical sciences
Full name of responsible person
Dr.Afsaneh Norouzi
Position
Asistant professor, Anesthesiologist
Other areas of specialty/work
Street address
Valieasr hospital, Emam khomeyni street
City
Arak
Postal code
Phone
+98 86 1222 2003
Fax
Email
norouzi.a@arakmu.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Arak university of medical sciences
Full name of responsible person
Dr. Afsaneh Norouzi
Position
asistant professor, anesthesiologist
Other areas of specialty/work
Street address
Valieasr hospital, Emam khomeyni street
City
Arak
Postal code
Phone
+98 86 1222 2003
Fax
Email
norouzi.a@arakmu.ac.ir , norouzi43@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Arak university of medical sciences
Full name of responsible person
Samira Mohamadi
Position
Medical student
Other areas of specialty/work
Street address
Valieasr hospital, Emam khomeyni street
City
Arak
Postal code
Phone
+98 86 1224 7041
Fax
Email
mohamadi.samira.15@gmail.com
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