

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 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
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Person responsible for updating data

Contact

Name of organization / entity
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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