Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Pharmacokinetic Alteration of Pethidine in Patients Following Lower-Limb Orthopedic Surgery and its Relationship with the Intensity of Pain in these Patients.

Protocol summary

Summary

The aim of the present study was to investigate possible relationship between blood levels of pethidine and intensity of pain in patients following orthopedic surgery in inferior limb. Twelve patients who underwent orthopedic surgery of the lower limbs and were classified as class I patients (according to the American society of anesthesiologists physical status classification) were included in the present single arm study. They were all between the age range of 18 and 35 years, having full consciousness and experiencing post-operative pain. Those undergoing emergency surgical operations and having abnormal paraclinical tests were excluded from the study. The study was conducted at Sina hospital. After the surgery, following the transference of the patient to the recovery section, 25 mg pethidine was injected intravenously using standard method for local (spinal) anesthesia for pain control. Then, 5, 30, 60 and 180 minutes after injection, blood samples were taken and concentration of pethidine in blood samples were measured by HPLC method. Moreover, patients' pain intensity was assessed on visual analogue scales. As secondary outcome measures, any possible adverse drug reactions were monitored. Finally, the possible relationship between pharmacokinetic alteration of pethidine and pain intensity of the patients undergoing lower-limb surgery was calculated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201508093106N28**
Registration date: **2015-12-24, 1394/10/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-12-24, 1394/10/03

Registrant information

Name

Farshad Hashemian

Name of organization / entity

Pharmaceutical Sciences Branch, Islamic Azad University (IAU)

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research Affairs, Islamic Azad University, Pharmaceutical Sciences Branch.

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2015-09-23, 1394/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Pharmacokinetic Alteration of Pethidine in Patients Following Lower-Limb Orthopedic Surgery and its Relationship with the Intensity of Pain in these Patients.

Public title

Pharmacokinetic Alteration of Pethidine in Patients Following Lower-Limb Orthopedic Surgery.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria include: Age between 18 and 35 years; Not having substance abuse; Having physical and mental health; Having post-operative pain; Having full consciousness; Being classified as class I patients (according to the American society of anesthesiologists physical status classification). Exclusion Criteria include: Pregnancy; Lactation; Having seizures; Having psychiatric disorders; Undergoing emergency surgical operations; Having abnormal paraclinical tests.

Age

From **18 years** old to **35 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **12**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University, Pharmaceutical Sciences Branch (IAUPS).

Street address

No.99 Yakhchal Street, Shariati Avenue.

City

Tehran

Postal code

1941933111

Approval date

2015-06-13, 1394/03/23

Ethics committee reference number

IR.IAU.PS.REC.1394.5

Health conditions studied

1

Description of health condition studied

Fracture of Lower Limb

ICD-10 code

T12

ICD-10 code description

Fracture of lower limb, level unspecified

Primary outcomes

1

Description

Assessment of pain intensity.

Timepoint

5, 30, 60 and 180 minutes after drug injection

Method of measurement

Based on Visual Analogue Scale (VAS)

2

Description

Measuring blood levels of pethidine

Timepoint

5, 30, 60 and 180 minutes after injection

Method of measurement

with HPLC Method

Secondary outcomes

1

Description

Adverse drug reactions.

Timepoint

5, 30, 60 and 180 minutes after injection of the drug.

Method of measurement

Observation and clinical studies.

Intervention groups

1

Description

After the surgery and following transference of the patients to the recovery section, 25 mg pethidine was injected intravenously.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr. Farshad Hashemian

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research Affairs, Islamic Azad University, Pharmaceutical Sciences Branch

Full name of responsible person

Dr. Sepideh Arbabi

Street address

No.99, Yakhchal St., Dr. Shariati Ave.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research Affairs, Islamic Azad University, Pharmaceutical Sciences Branch

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

Islamic Azad University, Pharmaceutical Sciences Branch, Faculty of Pharmacy

Full name of responsible person

Dr. Farshad Hashemian

Position

Dean of School of Pharmacy, Associate Professor/ Pharm.D., Pharmacotherapy Specialist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Position

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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University, Pharmaceutical Sciences Branch (IAUPS)

Full name of responsible person

Shima Afshar

Position

Pharm.D.

Other areas of specialty/work

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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