

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 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)

###### Phone

+98 21 2260 0037

###### Email address

hashemian.f@iaups.ac.ir

##### 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**

## 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**

**Street address**

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

**City**

Tehran

**Postal code**

1941933111

**Phone**

+98 21 2264 0056

**Fax**

**Email**

hashemian.f@iaups.ac.ir

**Web page address**

## Person responsible for scientific 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**

**Street address**

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

**City**

Tehran

**Postal code**

1941933111

**Phone**

+98 21 2264 0056

**Fax**

**Email**

hashemian.f@iaups.ac.ir

**Web page address**

## 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**

**Street address**

No.99, Yakhchal St. Shariati Ave.

**City**

Tehran

**Postal code**

**Phone**

+98 21 2264 0056

**Fax**

**Email**

afshar.shiima@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*