

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Comprasion of Effectiveness Oxycodone Pills and Pethidine Ampoule in Control of Patient's Shivering after Ingueinal Hernioraphy followed by Spinal Anesthesia

#### Protocol summary

##### Study aim

The aim of this study was to compare the efficacy of oxycodone and pethidine ampoule in control of shivering in patients undergoing spinal anaesthesia herniorrhaphy.

##### Design

A randomized controlled trial clinical trial with cross-over, double-blind, placebo

##### Settings and conduct

The study population consisted of patients with chills in recovery and operating room of Fatemi and Imam Khomeini hospitals in Ardabil. There will be two types of envelopes: Envelope A with pethidine syringe and placebo tablets, and Envelope B with syringes containing normal saline and oxy codon. Each disease will receive these envelopes depending on whether they have A or B code. The drug is prescribed before surgery.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include ASA I, II patients with post-spinal anaesthesia shivering with inguinal hernia diagnosis. Exclusion criteria included the history of pethidine or oxycodone sensitivity, history of peptic ulcer, systemic infection or immunodeficiency, history of use of monoamine oxidase inhibitor drugs, untreated hypothyroidism, benign prostatic hypertrophy, sickle cell disease, Addison They had significant bleeding during surgery and patients who did not undergo spinal anesthesia and became anesthetized.

##### Intervention groups

Pethidine ampoule will be given 0.4 mg/kg immediately after spinal anesthesia and 5 mg oxycodone tablet half an hour before surgery.

##### Main outcome variables

The incidence and severity of shivering will be assessed during and after surgery and their shivering score will be recorded.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181006041248N1**

Registration date: **2020-01-05, 1398/10/15**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-01-05, 1398/10/15**

Update count: **0**

##### Registration date

2020-01-05, 1398/10/15

##### Registrant information

##### Name

Saman Hayadokht

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 45 3323 2521

##### Email address

s.hayadokht@arums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-05-30, 1398/03/09

##### Expected recruitment end date

2020-01-29, 1398/11/09

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Comparison of Effectiveness Oxycodone Pills and Pethidine Ampoule in Control of Patient's Shivering after Inguinal Hernioraphy followed by Spinal Anesthesia

**Public title**

Evaluation of the Effect of Oxycodone Pills on Shivering Control

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients ASA I,II Patients who have been diagnosed with Inguinal Hernia after Spinal Anesthesia and have been Shivering

**Exclusion criteria:**

History of Allergy to Pethidine or Oxycodone History of Peptic Ulcer, Systemic Infection, or Immune Deficiency History of Taking MAO Inhibitors Untreated Hypothyroidism Benign Prostatic Hypertrophy Addison Diseases Uterine Stenosis Seizure Disorders Patients who have had Significant Bleeding during Surgery Patients who do not have Spinal Anesthesia and become anesthetized Under 18 years of age over 65 years old

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **110**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients will be prepared randomly assigned in two Groups: Pethidine and Oxycodone. This is two blinded study. Each morning before surgery, the Number of Surgeries and the Number of Medications required by the Prescriber will be Available. There will be two Envelopes. Case A has Pethidine and Placebo Pills and the Envelope B contains a Syringe containing Normal Saline and an Oxycodone Pill. Any Disease based on the Code A or B they will receive these Envelopes. The Prescription is prescribed before Surgery.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

This Study is a Double Blind Clinical Trial. In this Study, 110 Patients were diagnosed with Inguinal Hernia for Random Allocation of Pethidine and Oxycodone each Day before Surgery the Number of Surgeries and the Number of required by the Presenter the Plan will be ready. There will be two types of Envelopes. Case A has Pethidine and Placebo Pills and the Envelope B contains a Syringe containing Normal Saline and an Oxycodone Pill. Any Disease based on the Code A or B they will receive these Envelopes. The Prescription is prescribed before Surgery.

**Placebo**

Used

**Assignment**

Crossover

**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**

Ardabil, Azadegan Town, Second Block, Second Alley

**City**

Ardabil

**Province**

Ardabil

**Postal code**

53141-56198

**Approval date**

2017-12-10, 1396/09/19

**Ethics committee reference number**

IR.ARUMS.REC.1396.158

**Health conditions studied****1****Description of health condition studied**

Shivering

**ICD-10 code**

T 88.5

**ICD-10 code description**

Other complication of anesthesia

**Primary outcomes****1****Description**

Incidence of shivering during surgery and after surgery

**Timepoint**

During surgery, in recovery and in section

**Method of measurement**

Observation

**Secondary outcomes****1****Description**

Nausea and vomiting

**Timepoint**

1, 6, 12 and 24 hour intervals

**Method of measurement**

Question from the patient

**Intervention groups**

1

**Description**

Intervention group: There will be two types of envelopes: Packet A with pethidine syringe and placebo tablets, and B envelope with syringes containing normal saline and oxycodon. Pethidine will be given 0.4 mg / kg immediately after spinal anesthesia and oxycodone 5 mg tablet half an hour before surgery

**Category**

Prevention

**Recruitment centers**

1

**Recruitment center****Name of recruitment center**

Fatemi and Imam Khomeini Hospitals of Ardabil

**Full name of responsible person**

Saman Hayadokht

**Street address**

Emam Khomeini Hospital, Ataii Ave., Ardabil, Iran

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Emamhe@arums.ac.ir

**Sponsors / Funding sources**

1

**Sponsor****Name of organization / entity**

Ardabil University of Medical Sciences

**Full name of responsible person**

Ghodrat Akhavan Akbari

**Street address**

Ardabil University of Medical Sciences, Ardabil  
University of Medical Sciences

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**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**

Saman Hayadokht

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

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plaque 51

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ardabil University of Medical Sciences

**Full name of responsible person**

Ghodrat Akhavanakbari

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

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**Person responsible for updating data****Contact****Name of organization / entity**

Ardabil University of Medical Sciences

**Full name of responsible person**

Saman Hayadokht

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

Ardabil - Azadegan Town - Second Alley - Second Block - No. 51

**City****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**

No more information

**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