

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Ardabil University of Medical Sciences

Full name of responsible person

Ghodrat Akhavan Akbari

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Ardabil University of Medical Sciences, Ardabil
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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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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact
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Position
Resident
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Block - No. 51
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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