

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Comparison of the effect of Methadone and Morphine on postoperative pain scale following thoracic surgery in opium addicted patients

Protocol summary

Summary

Objectives: The main objective of this study is evaluation and comparison of analgesic effect of Methadone and Morphine on postoperative pain following thoracic surgery in opium addicted patients. Design: This is a double blind study on 60 patients undergoing elective thoracic surgery. Setting and conduct: The patients will be divided into two groups of 30 ones. The method of randomization is minimizing. However the patients do not know the administered medicine. After measuring patient's vital signs general anesthesia will be given to them identically. The severity of pain is evaluated by an anesthesiologist who is blind to administered drug at the end of surgery in recovery room and during first 24 hours, using Visual Analogue Scale. During first 24 hours after surgery Meperidine is administered if the patient asks analgesic. Also severity of pain is recorded at first, third, 6th, 12th and 24th hour after surgery using Visual Analogue Scale. Then these data will be analyzed by using computer. Participants including major eligibility criteria: Inclusion criteria are: American Association of Anesthesiologists' (ASA) classification of I or II; age 20 -65. Exclusion criteria are: ASA classification of 3-6 (severe systemic disorders); less than one year period of addiction. Intervention: In first group 0.1mg Methadone and in second group 0.1mg Morphine is injected 30 minutes before induction of anesthesia. Main outcome measures: The severity of pain is evaluated by an anesthesiologist at the end of surgery in recovery room and during first 24 hours, using Visual Analogue Scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013010912074N1**

Registration date: **2013-02-18, 1391/11/30**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-02-18, 1391/11/30

Registrant information

Name

Hoseyn Taravati

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 1223 5011

Email address

shafahospital@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kerman University of Medical Sciences

Expected recruitment start date

2012-10-22, 1391/08/01

Expected recruitment end date

2013-04-21, 1392/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Methadone and Morphine on postoperative pain scale following thoracic surgery in opium addicted patients

Public title

Comparison of the effect of Methadone and Morphine on postoperative pain following surgery in opium addicted

patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria are: American Association of Anesthesiologists' (ASA) classification of I or II; age 20-65; having thoracic surgery (thoracotomy or incision's extent of 10cm, without removal of rib and duration of 3 hours or less); more than 12 months history of opium addiction (inhalation form) as described by DSM-IV codes and after obtaining informed consent. Exclusion criteria are: ASA classification of 3-6 (severe systemic disorders such as Chronic Renal Failure and Chronic Heart Failure); non addicted patients; less than 12 months duration of addiction; addiction to drugs other than opium; consuming less than or more than 390mg of opium per day.

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Ethics committee of Kerman University of Medical Sciences

Street address

Jomhoori boulevard

City

Kerman

Postal code

Approval date

2012-02-27, 1390/12/08

Ethics committee reference number

k/90/314

Health conditions studied

1

Description of health condition studied

Opium Addiction

ICD-10 code

F11

ICD-10 code description

Mental and behavioural disorders due to use of opioids

Primary outcomes

1

Description

severity of pain

Timepoint

at first, third, 6th, 12th and 24th hour of post operation time

Method of measurement

Visual Analogue Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: Methadone (each ampoule contains 10mg Methadone made by Daroopakhsh) with dosage of 0.1mg/kg injecting IV 30 minutes before induction of anesthesia.

Category

Treatment - Drugs

2

Description

control: Morphine (each ampoule contains 10mg Morphine made by Daroopakhsh) with dosage of 0.1mg/kg injecting IV 30 minutes before induction of anesthesia.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipoor Hospital of Kerman

Full name of responsible person

Marziyeh Khosravi

Street address

Afzalipoor Hospital, Zendan Square

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kerman University of
Medical Sciences

Full name of responsible person

Fatemeh Hassani

Street address

Tahmasbabad Square, Ebnesina Street

City

Kerman

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, Kerman 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**

Kerman University of Medical Sciences

Full name of responsible person

Marziyeh Khosravi

Position

Resident of anesthesiology

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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