

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Effects of Intraoperative Morphine and Methadone on Postoperative Pain Control in Opioid Addicted Patients undergoing Orthopedic Surgery

Protocol summary

Study aim

Comparing the effect of morphine and methadone on control the postoperative pain in opium addict patients undergoing orthopedic surgery.

Design

A randomized, parallel, clinical trial with blinded care provider, outcome assessment and the patient

Settings and conduct

This randomized, double-blinded study will be performed in a tertiary healthcare center which is a referral center for orthopedic surgery. All the patients will be randomized to two study groups to receive morphine (0.15 mg/kg) or methadone (0.15 mg/kg) during the operation.

Participants/Inclusion and exclusion criteria

Opium-dependent patients, aging between 18-78 years scheduled for major orthopedic surgeries will be included. The patients with ASA class III and IV, those receiving antidepressant and anticonvulsant medications and those with a history of hypersensitivity reaction to methadone and morphine will be excluded.

Intervention groups

1. Intramuscular injection (deltoid muscle) of 0.15 mg/kg methadone hydrochloride one hour before termination of the surgery. 2. Intramuscular injection (deltoid muscle) of 0.15 mg/kg morphine sulphate hydrochloride one hour before termination of the surgery.

Main outcome variables

Postoperative pain, postoperative nausea and vomiting, need for rescue analgesic, drug adverse effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090912002445N7**

Registration date: **2018-05-21, 1397/02/31**

Registration timing: **retrospective**

Last update: **2018-05-21, 1397/02/31**

Update count: **0**

Registration date

2018-05-21, 1397/02/31

Registrant information

Name

Fariborz Ghaffarpasand

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4259

Email address

ghafarf@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-10-01, 1395/07/10

Expected recruitment end date

2017-10-01, 1396/07/09

Actual recruitment start date

2016-10-01, 1395/07/10

Actual recruitment end date

2017-10-01, 1396/07/09

Trial completion date

empty

Scientific title

Effects of Intraoperative Morphine and Methadone on Postoperative Pain Control in Opioid Addicted Patients undergoing Orthopedic Surgery

Public title

Morphine and methadone for postoperative pain control

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

ASA Class I and II Opium Addict Elective orthopedic surgery

Exclusion criteria:

ASA Class III and IV Preoperative antidepressant and anticoagulant medication Hypersensitivity to morphine Hypersensitivity to methadone

Age

From **18 years** old to **78 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **60**

Actual sample size reached: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

All the patients will be randomized to two study groups using a computerized random digit generator based in the patients' admission number.

Blinding (investigator's opinion)

Double blinded

Blinding description

This will be a double-blinded randomized clinical trial. The medications will be prepared in the same form in dark syringes and will be given to the anesthesiologist who is not aware of the content. The nurse who will record the patient postoperative pain is also unaware of the study group. The patients are also blinded toward to study intervention.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Medical Ethics Committee of Shiraz University of Medical Sciences

Street address

Zand Avenue

City

Shiraz

Province

Fars

Postal code

71973-11351

Approval date

2016-03-03, 1394/12/13

Ethics committee reference number

IR.SUMS.MED.REC.1394.509

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

After surgery pain

ICD-10 code

R52

ICD-10 code description

Pain, not elsewhere classified

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

Postoperative pain

Timepoint

0, 1, 3, 6, 12, 24 hours after operation

Method of measurement

Visual analogue scale

2**Description**

Postoperative nausea and vomiting

Timepoint

0, 1, 3, 6, 12, 24 hours after operation

Method of measurement

Visual analogue scale

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

Need for rescue analgesia

Timepoint

24 hours after the surgery

Method of measurement

Administered dosage in milligrams

Intervention groups**1****Description**

Intervention group: Intramuscular methadone (0.15 mg/kg) one hour before termination of surgery

Category

Treatment - Drugs

2

Description

Control group: Intramuscular morphine sulphate (0.15 mg/kg) one hour before termination of surgery

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Chamran Hospital

Full name of responsible person

Reza Raeesi Estabragh

Street address

Chamran avenue

City

Shiraz

Province

Fars

Postal code

71973-11351

Phone

+98 71 3647 4270

Email

r.raeesi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Seyed Basir Hashemi

Street address

Zand Avenue

City

Shiraz

Province

Fars

Postal code

71345-1876

Phone

+98 71 3235 7282

Email

hashemib@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Reza Raeesi Estabragh

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Anesthesiology and Intensive Care Research Center,
Nemazi Hospital, Namazi Square

City

Shiraz

Province

Fars

Postal code

7194815644

Phone

+98 71 3647 4270

Email

r.raeesi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Reza Raeesi Estabragh

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Anesthesiology and Intensive Care Research Center,
Nemazi Hospital, Namazi Square

City

Shiraz

Province

Fars

Postal code

7194815644

Phone

+98 71 3647 4270

Email

r.raeesi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Fariborz Ghaffarpasand

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

Street address

Shahid Chamran hospital, Chamran Avenue

City

Shiraz

Province

Fars

Postal code

71345-1876

Phone

+98 71 3625 4206

Fax**Email**

ghafarf@sums.ac.ir

Web page address

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

There is no further 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