Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Fariborz Ghaffarpasand

Name of organization / entity
Shiraz University of Medical Sciences

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Iran (Islamic Republic of)

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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 vomitting

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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
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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
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