

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the Postoperative Pain in Major Orthopedic Surgery in Patients Addicted to Opium.

Protocol summary

Summary

Objectives: To investigate the effects of morphine and methadone for pain control after orthopedic surgery in patients addicted to opioids. Research Design: A randomized, double-blind, clinical trial Inclusion criteria: Opium -addicted patients, aged of 18-70 years undergoing major orthopedic surgeries. Exclusion criteria: Patients with a history of myocardial infarction, heart failure, patients with ASA above III, using anti-depressant, allergy to the drugs and patients requiring ICU after surgery. 68 Patients are randomly divided into two groups MTD (methadone) and M (morphine). However, 0.15 mg/kg morphine or methadone given to the patient an hour before the completion of the surgery. Patients in recovery room were treated according to the severity of pain as follows: morphine 1 mg every 5 minutes with pain score 6-4, and 2 mg every 5 minutes with pain score of 10 -7. While, blood pressure and breathing were monitoring, until the pain intensity reaches to less than 4. In the surgery ward morphine pump was used for patients in the both groups, as follows, a solution of 20 cc, 0.5 mg per/cc with 1 mg or 2 CC bolus and interval locked out seven minutes and the maximum dose of 25 mg or 50 cc every 4 hours. At 0, 1, 3, 6 and 24 hours after surgery pain parameters (both in the time of the rest and activity), pruritus, nausea and vomiting, urinary retention, sedation and degree of patient satisfaction measured and data were recorded in a special form. Pain Score, patient satisfaction and degree of sedation were measured via NRS, four point categorical scale and Wilson, respectively.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014100919470N1**

Registration date: **2015-01-09, 1393/10/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-01-09, 1393/10/19

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4270

Email address

masihif@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Shiraz University of Medical Science

Expected recruitment start date

2014-02-01, 1392/11/12

Expected recruitment end date

2014-10-01, 1393/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Postoperative Pain in Major Orthopedic Surgery in Patients Addicted to Opium.

Public title

Comparison of Morphine and Methadone on Postoperative Pain of Opioid Addicted Patients in Major Orthopedic Surgery

Purpose

Supportive

Inclusion/Exclusion criteria
Inclusion criteria: opium -addicted patients, aged of 18-70 years undergoing major orthopedic surgeries.
Exclusion criteria: patients with a history of myocardial infarction, heart failure, patients with ASA class above III, patients using anti-depressant drugs, a history of allergy to the drugs and patients who need ICU after surgery.

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **68**

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 Shiraz University of Medical Sciences

Street address

Central Building of Shiraz University of Medical Sciences, Zand Street

City

Shiraz

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

CP-P-9356-5676

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

2

Description of health condition studied

Orthopaedic Surgery

ICD-10 code

M96.6

ICD-10 code description

Fracture of Bone following Insertion of Orthopaedic Implant, Joint Prosthesis, or Bone Plate

Primary outcomes

1

Description

Evaluation of the postoperative pain in major orthopedic surgery in patients addicted to opium.

Timepoint

Immediately after surgery and one hour, three hours, six hours and 24 hours after surgery.

Method of measurement

NRS

Secondary outcomes

1

Description

Patient's satisfaction

Timepoint

Immediately after surgery and one hour, three hours, six hours and 24 hours after surgery.

Method of measurement

Four Point Categorical Scale

Intervention groups

1

Description

Intervention Group 1: 0.15 mg/kg Morphine Given to the Patients an Hour before the Completion of the Surgery

Category

Treatment - Drugs

2

Description

Intervention Group 1: 0.15 mg/kg Methadone Given to the Patients an Hour before the Completion of the Surgery

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Chamran Hospital

Full name of responsible person

Afsoon Aleepour

Street address

Chamran Hospital, Chamran Boulevard

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Shiraz University of Medical Sciences

Full name of responsible person

Dr Seed Basir Hashemi

Street address

Vice Chancellor for Research, Shiraz University of Medical Sciences, 7th floor, Central Building of Shiraz University of Medical Sciences, Zand Street

City

Shiraz

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, Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Afsoon Aleepour

Position

Physician, Anesthesiology Resident

Other areas of specialty/work

Street address

Anesthesiology Department, Shahid Faghihi Hospital, Zand street

City

Shiraz

Postal code

Phone

+98 71 3235 7282

Fax

Email

afsoonaalipoor@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University Of Medical Sciences

Full name of responsible person

Dr Hedayatollah Akhlagh

Position

Anesthesiologist, Pain Fellowship

Other areas of specialty/work

Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

City

Shiraz

Postal code

Phone

+98 71 3647 4270

Fax

Email

akhlaghh@sums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Farzaneh Masihi

Position

English Consultant, Anesthesiology Research Center Staff

Other areas of specialty/work

Street address

Anesthesiology Office, Namazi Hospital

City

Shiraz

Postal code

Phone

+98 71 3647 4270

Fax

Email

masihifarzaneh@yahoo.com

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