Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

Comparison of the effect of morphine versus morphine/haloperidol on postoperative pain management in opioid addicted patients undergoing orthopedic surgery

Protocol summary

Summary

Objectives: The aim of this study was to compare the effect of morphine versus morphine/haloperidol on postoperative pain management in opioid addicted patients undergoing orthopedic surgery. Design: We selected 101 male opium addicts, aged 20 to 50 years old, undergoing femoral or tibial fracture fixation during the years 2008-2009, with American Society of Anesthesiologist physical state class I and II. Setting and Conduct: In the recovery unit, pain severity was measured with the Categorical Scaling Form, a horizontal line with anchors of 'no pain', 'mild', 'moderate', 'severe' and 'worst possible pain'. Pain scores were calculated by zero for 'no pain', 1 for 'mild', 2 for 'moderate', 3 for 'severe' and 4 for 'worst possible pain'. In the first episode of pain, the forms were completed and the medications were given according to the study groups. Then the forms were completed every half hour till 2 hour in the recovery unit. Patients with next episodes of 'mild' to 'moderate' pain would receive 0.07 mg/kg morphine and those with 'severe' or 'worst possible' pain would receive 0.1mg/kg morphine additionally. Participants: Opium addict male patients between 20 to 50 years old, undergoing fixation of femoral or tibial fractures with American Society of Anesthesiologist physical state class I and II Exclusion criteria: Patients with psychological disorder or using related medications Intervention: Receiving 0.1mg/kg morphine plus either 20 mg Haloperidol or 4cc Normal saline intravenously Main Outcome measures: Pain score, Total morphine consumption.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013111115379N1**

Registration date: **2015-06-08, 1394/03/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-06-08, 1394/03/18

Registrant information

Name

Tahere Jowkar

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Self Support

Expected recruitment start date

2008-06-22, 1387/04/02

Expected recruitment end date

2009-06-22, 1388/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of morphine versus morphine/haloperidol on postoperative pain

management in opioid addicted patients undergoing orthopedic surgery

Public title
Reducing postoperative pain in addict patients with haloperidol
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Opium addict, male patients, between 20 to 50 years old, undergoing fixation of femoral or tibial fractures, according to the ranking system of American Society of Anesthesiologist (ASA) with physical state class I and II Exclusion criteria: Patients with psychological disorder or using any related medications, renal and hepatic disorder, benign prostate hyperplasia, glaucoma, and a history of reaction to haloperidol or extra pyramidal syndrome
Age
From **20 years** old to **50 years** old
Gender
Male

Phase
3
Groups that have been masked
No information
Sample size
Target sample size:
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Randomization was done with sequential simple sampling method. Patients with odd and even file numbers were considered as haloperidol and placebo groups, respectively. The study was double-blinded, placebo controlled, randomized trial. The patients, the nurse giving the medications and the researcher filling the forms were all blind to the study groups. The medications were prepared by a staff not involved in the study. Fifty one syringes, labeled "A", were filled with 4 cc haloperidol (20 mg) while Fifty syringes, labeled "B", were filled with 4 cc normal saline. In the first episode of pain in the recovery unit, patients with odd file numbers received syringe "A" and those with even file numbers received syringe "B. The study was double-blinded, placebo controlled, randomized trial. The patients, the nurse giving the medications and the researcher filling the forms were all blind to the study groups. The medications were prepared by a staff not involved in the study. Fifty syringes, labeled "A", were filled with 4 cc normal saline while Fifty one syringes, labeled "B", were filled with 4 cc haloperidol (20 mg). In the first episode of pain in the recovery unit, patients with odd file numbers received syringe "A" and those with even file numbers received syringe "B".

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shiraz University of Medical Science
Street address
Shiraz University of Medical Sciences, Zand St.
City
Shiraz
Postal code
7134814336
Approval date
2008-05-17, 1387/02/28
Ethics committee reference number
CT-87-3951

Health conditions studied

1

Description of health condition studied
Postoperative pain
ICD-10 code
G89.18, T8
ICD-10 code description
Other acute postprocedural pain; Other complications of procedures, not elsewhere classified

Primary outcomes

1

Description
Pain score
Timepoint
First episode of pain in recovery unit, 30 minute later, 1 hour later, 1.5 hour later and 2 hour later
Method of measurement
Categorical Scaling Form

2

Description
Total morphine dose consumption
Timepoint
In each episode of pain in recovery unit injected morphine dose is recorded in milligram
Method of measurement
Summation of injected morphine doses in recovery unit

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Morphine 0.1 mg/kg plus 20 mg haloperidol, just in the first episode of pain post operation, all intravenously
Category
Treatment - Drugs

2

Description
Control group: Morphine 0.1 mg/kg plus 4cc normal saline, just in the first episode of pain postoperation, all intravenously
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Chamran Hospital
Full name of responsible person
Tahere Jowkar, General Practitioner
Street address
Recovery Unit, Operation Room, Chamran Hospital, Chamran Blvd.
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor of Research, Shiraz University of Medical Sciences
Full name of responsible person
Seyed Basir Hashemi
Street address
7th floor, Shiraz University of Medical Sciences, Zand St.
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 of 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
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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