

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 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

+98 74 3322 3847

Email address

tjowkar@yahoo.co.uk

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

Name of organization / entity

Rajai Hospital

Full name of responsible person

Asif Pervez Kazemi

Position

Anesthesiologist

Other areas of specialty/work

Street address

Rajai Hospital, Chamran Blvd.

City

Shiraz

Postal code

Phone

+98 71 3636 4001

Fax

Email

ap_kazemi@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rajai Hospital

Full name of responsible person

Asif Pervez Kazemi

Position

Anesthesiologist

Other areas of specialty/work

Street address

Rajai Hospital, Chamran Blvd.

City

Shiraz

Postal code

Phone

+98 71 3636 4001

Fax

Email

ap_kazemi@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Tahere Jowkar

Position

General Practitioner

Other areas of specialty/work**Street address**

Faculty of Medicine, Shiraz University of Medical
Sciences, Zand St.

City

Shiraz

Postal code**Phone****Fax****Email**

tjowkar@yahoo.co.uk

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