

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The comparison of postoperative analgesic effect between Morphine-Apotel and Cetorolac alone with Intravenous patient control analgesia in patients with fracture candidate for the plating surgery in Emam Reza Hospital ,Birjand 1394

Protocol summary

Summary

This study was performed to compare the analgesic effects between Morphine-Apotel and Ketorolac alone with Intravenous patient control analgesia in patients with fracture candidate for plating surgery. All patients with fracture, candidate for plating surgery, aged 18 to 50, who underwent general anesthesia were included and patients who were addicted to opium and had contraindication for general anesthesia were excluded. Study population included all fractures candidate for plating surgery and sampling size was estimated 110 patients. The study was performed as double-blind clinical trial on 1394. Patients were randomly divided to Morphine-Apotel or "Ketorolac" Group. Percutaneous control intravenous anesthesia was administered for patients 15 minutes after entry the recovery. In Morphine-Apotel group the pump was started with a rate of 5 milliliter per hour and dosage of 0.5 milligram per kilogram Morphine plus 40 milligram per kilogram Apotel and in Ketorolac group with the same specifications and dosage of 1 milligram per kilogram. A Questionnaire containing demographic informations, drug groups and degree of pain measured with "Visual Analogue Scale" 0, 6 and 12 hours after surgery, were recorded for all patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015091217607N2**
Registration date: **2015-11-10, 1394/08/19**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-11-10, 1394/08/19

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Birjand University Of Medical Sciences

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-07-23, 1394/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of postoperative analgesic effect between Morphine-Apotel and Cetorolac alone with Intravenous patient control analgesia in patients with fracture candidate for the plating surgery in Emam Reza Hospital ,Birjand 1394

Public title

the comparison of analgesic effect between Morphin-Apotel and Cetorolac alone after plating surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients aged 18-50; all fracture; candidate for plating surgery who underwent general anesthesia . Exclusion criteria: Patients who underwent spinal or epidural anesthesia; had contraindications for general anesthesia; Patients who were opium addict; Patients with coagulative disorder; platet count under 100000; Patients with chronic renal failure; creatinine levels more than 1.5.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Not 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

Emam reza hospital

Street address

Taleqani avenue

City

Birjand

Postal code

Approval date

2015-05-24, 1394/03/03

Ethics committee reference number

ir.bums.1394.25

Health conditions studied

1

Description of health condition studied

Injury of unspecified body region

ICD-10 code

T14,R52

ICD-10 code description

Injury of unspecified body region, Pain, not elsewhere classified

Primary outcomes

1

Description

pain

Timepoint

evry 6 hour

Method of measurement

Visual Analuge Scale

Secondary outcomes

empty

Intervention groups

1

Description

Ketorolac 1 milligrams per kilograms

Category

Treatment - Drugs

2

Description

apotel 40 milligrams per kilograms and morphine 0.5 milligrams per kilograms.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Dr Pooya Derakhshan

Street address

City

Birjand

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research Birjand University Of

Medical Sciences

Full name of responsible person

Dr Asghar Zarban

Street address

Vice Chancellor for Research, Birjand University of
Medical Science, Birjand

City

Birjand

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 Birjand 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

Birjand University of medical science

Full name of responsible person

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Position

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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