

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Comparison of analgesic effect of intra-articular and peri-articular injection of morphine and ketamine compound following arthrotomy surgery

Protocol summary

Summary

After obtaining written informed consent from eligible patients, and getting an approval from Ethics committee of Ahvaz Jundishapur University of Medical Sciences, a double-blind prospective, randomized study will be done among patients with elective surgery. Spinal anesthesia with 12.5 mg Marcaine will be done in both groups equally. Inclusion criteria: the patient's satisfaction; age between 20 and 60 years old. Exclusion criteria: the lack of patient's satisfaction to spinal anesthesia; history of hypnotics or narcotics throughout 24 hours before the surgery; history of drug abuse, or alcohol-dependency; contraindication of morphine or Ketamine. Patients will be randomly allocated into three groups according to table of random numbers. Groups "one" and "two" will receive 5 mg of intravenous (IV)morphine with 0.5 mg/kg of (IV)ketamine intra-articular and 5 mg of intravenous (IV)morphine with 0.5 mg/kg of (IV)ketamine peri-articular, respectively. Postoperative pain and needs for analgesics will be measured at 1, 2, 4, 6, 12 and 24 hours after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013021912531N1**

Registration date: **2013-07-01, 1392/04/10**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-07-01, 1392/04/10

Registrant information

Name

Kamran Mahmodi

Name of organization / entity

Ahvaz Jundishapur 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

Vice chancellor for research, Ahvaz University of Medical Sciences

Expected recruitment start date

2013-09-01, 1392/06/10

Expected recruitment end date

2014-03-01, 1392/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of analgesic effect of intra-articular and peri-articular injection of morphine and ketamine compound following arthrotomy surgery

Public title

Comparison of analgesic effect of intra-articular and peri-articular injection of morphine and ketamine compound following arthrotomy surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: the patient's satisfaction; age between

20 and 60 years old. Exclusion criteria: the lack of patient's satisfaction to spinal anesthesia; history of hypnotics or narcotics throughout 24 hours before the surgery; history of drug abuse, or alcohol- dependency; contraindication of morphin or Ketamine.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Patients are assigned randomly to 2 groups using a computerized allocation schedule for the coded syringes containing the study drugs. After randomization, the coded syringes are prepared by an anesthesiologist not involve in the administration of the drug, patient care and data collection.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

No.12, Chamber Sadaf, Golestan Blvd

City

Ahvaz

Postal code

6135733777

Approval date

2013-04-20, 1392/01/31

Ethics committee reference number

ETH-622

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

R52.0

ICD-10 code description

Acute pain

Primary outcomes

1

Description

Pain

Timepoint

1, 2, 4, 6, 12 and 24 hour after surgery

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Opioid Consumption

Timepoint

24 hours after surgery

Method of measurement

Milligrams

Intervention groups

1

Description

Drugs: 1-Ketamine: Dose: 0.5mg/kg Number of using: Once Factory name: Rotexmedica Manufacturing Country's Name: Germany Location prescribed: intra-articular Administration time: 10 minutes before the end of surgery 2- Morphin: Dose: 0.5 mg Number of using: Once Factory name: Daroupakhsh Manufacturing Country's Name: Iran Location prescribed: intra-articular Administration time: 10 minutes before the end of surgery

Category

Treatment - Drugs

2

Description

Drugs: 1-Ketamine: Dose: 0.5mg/kg Number of using: Once Factory name: Rotexmedica Manufacturing Country's Name: Germany Location prescribed: peri-articular Administration time: 10 minutes before the end of surgery 2- Morphin: Dose: 0.5 mg Number of using: Once Factory name: Daroupakhsh Manufacturing Country's Name: Iran Location prescribed: peri-articular Administration time: 10 minutes before the end of surgery

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Educational Hospital

Full name of responsible person

Dr. Reza Akhundzadeh

Street address

No. 307, Kokab Street, Masters Alley, Golestan Blvd.

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ahvaz Jundishapur
University of Medical Sciences

Full name of responsible person

Dr. Mostafa Feghhi

Street address

No. 21, Ave. 1, Golestan Blvd.

City

Ahvaz

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, Ahvaz Jundishapur
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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Kamran Mahmodi

Position

Resident of Anesthesia

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

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Position

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Person responsible for updating data

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