

# 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

+98 61 1222 0168

##### Email address

mahmodi.k@ajums.ac.ir

##### 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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mostafafatahi777@gmail.com

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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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*