

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### Comparison of analgesic effects of intraarticular ketamine- Methylprednisolone and Methylprednisolone in knee osteoarthritis patients

#### Protocol summary

##### Summary

This study is a randomized double-blind clinical trial. The aim of this study is comparison of analgesic effects of intraarticular ketamine- methylprednisolone versus methylprednisolone in knee osteoarthritis patients. People under study are 70 patients 35-80 years old with history of at least one month of unsuccessful treatment and positive radiological findings. Patients with a history of drug addiction and fractures of the Knee and meniscal and ligament injuries of the knee will be excluded. Patients are randomly divided into two groups. The first group received ketamine- methylprednisolone. Second group just received methylprednisolone. Patients and doctor are not aware of the content of the injected drug and The drug is prepared by the nurse anesthesia. Orthopedic doctor without a knowledge of the type of drug injected into the joint (Super lateral patellar pouch). The severity of pain in patient were assessed with a visual analog scale one and three months after injection.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014111119902N1**

Registration date: **2015-01-10, 1393/10/20**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-01-10, 1393/10/20

##### Registrant information

###### Name

Hanoon Sadoni

###### Name of organization / entity

Ahvaz Jondishapour University Of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 3221 6504

###### Email address

sadoni-h@ajums.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Ahvaz Jondishapour University of Medical Sciences

###### Expected recruitment start date

2014-08-23, 1393/06/01

###### Expected recruitment end date

2015-02-20, 1393/12/01

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Comparison of analgesic effects of intraarticular ketamine- Methylprednisolone and Methylprednisolone in knee osteoarthritis patients

###### Public title

The Analgesic Effects Of Ketamine- Methylprednisolone versus Methyl Prednisolone in Knee Osteoarthritis Patients

###### Purpose

Prevention

###### Inclusion/Exclusion criteria

Inclusion criteria: Pain due to arthritis; at least one month of unsuccessful treatment; positive radiological findings. Exclusion criteria: Pain due to inflammatory diseases; history of fractures of the knee; ankylosis of

the knee; previous deformity such as genu varum; immunodeficiency; infection at the injection site; drug addiction; meniscal and ligament injuries of the knee; coagulation disorders.

#### Age

From **35 years** old to **80 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **70**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Ahvaz Jondishapour University Of Medical Sciences

##### Street address

Vice chancellor for Research & Technology, Ground floor, central library, Golestan Blvd., Ahvaz Jondishapour University of Medical Sciences, Ahvaz

##### City

Ahvaz

##### Postal code

##### Approval date

2014-09-13, 1393/06/22

##### Ethics committee reference number

Ajums.REC.1393.320

## Health conditions studied

### 1

#### Description of health condition studied

pain

#### ICD-10 code

Y45

#### ICD-10 code description

Analgesics, antipyretics and anti-inflammatory drugs

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

One and Three Months After Injection

#### Method of measurement

visual analog scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Group I: Intra-articular injection of 40 mg/ml methylprednisolone and 1 ml sterile water in the operation room.

#### Category

Placebo

### 2

#### Description

Group II: Intra-articular injection of 40 mg/ml methylprednisolone and 0.5 mg/kg ketamine in the operating room.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Razi Hospital

##### Full name of responsible person

Ali Ghomeishi

##### Street address

Felestin St., Amanieh, The Razi Hospital, Ahvaz

##### City

Ahvaz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Ahvaz Jondishapour University of Medical Sciences

##### Full name of responsible person

Nader Saki

##### Street address

Office of Vice chancellor for research, Ahvaz Jondishapour University of Medical Sciences, Ground

Floor, Central Library, Golestan Blvd., Ahvaz  
Jondishapour University of Medical Sciences, Ahvaz

**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 Jondishapour  
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**

Imam Khomeini Hospital

**Full name of responsible person**

Reza Akhondzadeh

**Position**

Anesthesiologist

**Other areas of specialty/work**

**Street address**

Department of Anesthesiology, General Operating  
Room, Second floor of the Imam Khomeini Hospital,  
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**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Ahvaz Jondishapour University of Medical Sciences

**Full name of responsible person**

Hanoon Sadoni

**Position**

Specialist in Orthopedic

**Other areas of specialty/work**

**Street address**

College of Medicine, Golestan Blvd., Ahvaz  
Jondishapour University of Medical Sciences, Ahvaz

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Pain Research Center

**Full name of responsible person**

Sanaz Nazari

**Position**

Nurse Anesthesia

**Other areas of specialty/work**

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Pain Research Center, Fourth floor, Imam Khomeini  
Hospital, Shahid Ahvazian St., Ahvaz

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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*