

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

**To investigate the post - operative analgesic effect of intra - articular magnesium sulfate and Bupivacaine compared with Tramadol and Bupivacaine after knee arthroscopic surgeries.**

### Protocol summary

#### Summary

Objective: To compare the post - operative analgesic effect of intra - articular magnesium sulfate and Bupivacaine with Tramadol and Bupivacaine after knee arthroscopic surgeries. Study design: A single blind randomized clinical trial. Inclusion criteria: Aged over 19 and under 65 years old; (ASA I-II). Exclusion criteria: Biopsy or simple knee washing; chronic use of opium or tramadol. Methods: 43 patients undergoing arthroscopic knee surgery divided into two groups of 21 patients of each . The first intervention group (T): patients received 100 mg tramadol (50 mg / ml ampule, Tehran Chemie Pharmaceutical, Tehran, Iran) with 50 mg bupivacaine 0.25% (Bupivacaine-Milan 0.5%, Willy 20 MI, Mylan, France) so that the final volume of solution is adjusted to 20 ml with normal saline and injected into the joint at the end of the surgery. The second intervention group (M): patients received 2 g magnesium sulfate (magnesium sulfate 50%, 50 ml vial., Pasteur Institute of Iran, Tehran, Iran) with 0.5 mg bupivacaine (0.25%) as the final volume with saline solution will be 20 ml and injected at the end of the joint operation. The pain scores (VAS) assessed before surgical procedure, in the recovery room and 24 hours after surgery.] The morphine IV, PCA pumps and total morphine consumption, any side effects, and the percentage of satisfaction with the quality of analgesia were compared between the groups.

### General information

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT2016082719470N42**  
Registration date: **2017-10-01, 1396/07/09**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

#### Registration date

2017-10-01, 1396/07/09

#### Registrant information

##### Name

Farzaneh Masihi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3647 4270

##### Email address

masihif@sums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice Chancellor for Research, Shiraz University of Medical Sciences

#### Expected recruitment start date

2017-06-22, 1396/04/01

#### Expected recruitment end date

2017-10-23, 1396/08/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

To investigate the post - operative analgesic effect of intra - articular magnesium sulfate and Bupivacaine compared with Tramadol and Bupivacaine after knee arthroscopic surgeries.

#### Public title

To investigate the post - operative analgesic effect of

intra - articular magnesium sulfate / Bupivacaine compared with Tramadol / Bupivacaine after knee arthroscopic surgeries.

#### **Purpose**

Prevention

#### **Inclusion/Exclusion criteria**

Inclusion criteria: Aged over 19 and under 65 years old; (ASA I-II). Exclusion criteria: Biopsy or simple knee washing; chronic use of opium or tramadol.

#### **Age**

From **19 years** old to **65 years** old

#### **Gender**

Both

#### **Phase**

2-3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **43**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Single blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

Random Number Table is method for randomization.

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

##### **Street address**

Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

##### **City**

Shiraz

##### **Postal code**

#### **Approval date**

2017-04-21, 1396/02/01

#### **Ethics committee reference number**

IR.SUMS.MED.REC.1395.28

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

arthrosis of knee

#### **ICD-10 code**

M17

#### **ICD-10 code description**

Gonarthrosis [arthrosis of knee]

## **Primary outcomes**

### **1**

#### **Description**

Pain score

#### **Timepoint**

before surgical procedure, in the recovery and 24 hours after surgery

#### **Method of measurement**

VAS(visual analog scale)

### **2**

#### **Description**

The morphine IV, PCA pumps and total morphine consumption

#### **Timepoint**

24 hours after surgery at 2, 4, 6, 8, 12, 16, 20, and 24

#### **Method of measurement**

Observation

### **3**

#### **Description**

any side effects of analgesics

#### **Timepoint**

24 hours after surgery at 2, 4, 6, 8, 12, 16, 20, and 24

#### **Method of measurement**

Observation

## **Secondary outcomes**

### **1**

#### **Description**

patients stisfaction

#### **Timepoint**

After surgery in the ward

#### **Method of measurement**

Questionnaire

## **Intervention groups**

### **1**

#### **Description**

The first intervention group (T): patients received 100 mg tramadol (50 mg / ml ampoule, Tehran Chemie Pharmaceutical, Tehran, Iran) with 50 mg bupivacaine 0.25% (Bupivacaine-Milan 0.5%, Willy 20 MI, Mylan, France) so that the final volume of solution is adjusted to 20 ml with normal saline and injected into the joint at the end of the surgery.

#### **Category**

Treatment - Drugs

## 2

### Description

The second intervention group (M): patients received 2 g magnesium sulfate (magnesium sulfate 50%, 50 ml vial., Pasteur Institute of Iran, Tehran, Iran) with 0.5 mg bupivacaine (0.25%) as the final volume with saline solution will be 20 ml and injected at the end of the joint operation.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Chamran Hospital

##### Full name of responsible person

Afshin Zarei

##### Street address

Chamran Hospital, Chamran Boulevard

##### City

Shiraz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for Research, Shiraz University of Medical Sciences

##### Full name of responsible person

Dr Seed Basir Hashemi

##### Street address

Vice chancellor of research, 7th floor of central building of Shiraz University of Medical Sciences, Zand street

##### 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 for 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

Shiraz University of Medical Sciences

#### Full name of responsible person

Afshin Zarei

#### Position

anesthesiology resident/physician

#### Other areas of specialty/work

#### Street address

Anesthesiology Department- Faghihi Hospital- Zand Street

#### City

Shiraz

#### Postal code

#### Phone

+98 71 3647 4270

#### Fax

#### Email

masihifarzaneh@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Shiraz University of Medical Sciences

#### Full name of responsible person

Dr Sina Gafari

#### Position

Anesthesiologist, Transplant fellowship

#### Other areas of specialty/work

#### Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

#### City

Shiraz

#### Postal code

#### Phone

+98 71 3647 4270

#### Fax

#### Email

sighafari@sums.ac.ir

#### Web page address

## Person responsible for updating data

### Contact

#### Name of organization / entity

Shiraz University of Medical Sciences

#### Full name of responsible person

Farzaneh Masihi

#### Position

MS in english teaching ,BS in anesthesia/English Consultant

#### Other areas of specialty/work

#### Street address

5th floor, Mohammad Rasul Allah Research Tower, Khalili Street

#### City

Shiraz

**Postal code**

**Phone**

+98 71 3647 4270

**Fax**

**Email**

masihifarzaneh@yahoo.com

**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*