

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 satisfaction

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

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Anesthesiologist, Transplant fellowship

Other areas of specialty/work

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Full name of responsible person

Farzaneh Masihi

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MS in english teaching ,BS in anesthesia/English Consultant

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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