Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Ml, 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)
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+98 71 3647 4270
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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
Observasion

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
Observasion

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 Ml, 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

Name of organization / entity
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Full name of responsible person
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Position
Anesthesiologist, Transplant fellowship

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity
Shiraz University of Medical Sciences

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Farzaneh Masihi

Position
MS in english teaching ,BS in anesthesia/English Consultant

Other areas of specialty/work

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

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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