Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

Comparison of fentanyl and magnesium sulfate intrathecal and intraarticular in pain after knee arthroscopy

Protocol summary

Study aim
Comparison of fentanyl and magnesium sulfate intrathecal and intraarticular in pain after knee arthroscopy

Design
The study will be double blind and clinical trial.140 patients will be randomly divided into 4 groups. The groups are parallel. The trial phase is 3.

Settings and conduct
Patients With knee arthroscopyin Valiasr Hospital in Arak are divided into 4 groups by simple randomization with blocks.The study is double-blind in which outcome evaluator and data analyst and participant are kept blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria:18 to 60 years old, ASA class 1 and 2, no history of drug use, no history of chronic painkiller use, no allergy to the drugs used, no liver and kidney failure, absence of body mass index greater than 30, absence of cardiovascular problems and arrhythmia, absence of peripheral and central neuropathy, absence of local infection in the spinal area Exclusion criteria: patient's lack of consent to continue participating in the study, patient's refusal to perform spinal anesthesia, failure to perform spinal anesthesia

Intervention groups
Intervention group 1: 100 mg magnesium sulfate without preservative along with 15 mg bupivacaine 0.5% hyperbaric. Intervention group 2: 8 ml of 10% magnesium sulfate with 12 ml of distilled water and a total volume of 20 ml is administered intra-articularly. Intervention group: 50 micrograms of fentanyl along with 15 mg bupivacaine 0.5% hyperbar (heavy) will be Intervention group 4: 50 micrograms of fentanyl will be added to 19 ml of normal saline.

Main outcome variables
Pain-average analgesic drug consumption

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141209020258N181**
Registration date: **2023-02-25, 1401/12/06**
Registration timing: **prospective**

Last update: **2023-02-25, 1401/12/06**
Update count: **0**

Registration date
2023-02-25, 1401/12/06

Registrant information

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Name of organization / entity
Arak University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-03-11, 1401/12/20

Expected recruitment end date
2024-03-10, 1402/12/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of fentanyl and magnesium sulfate intrathecal and intraarticular in pain after knee arthroscopy

Public title
Comparison of fentanyl and magnesium sulfate intrathecal and intraarticular in pain after knee arthroscopy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
18 to 60 years both sexes ASA class 1 and 2 No history of drug use No history of chronic use of painkillers Lack of sensitivity to the drugs used in this study Absence of liver and kidney failure Absence of underlying disease such as high blood pressure, diabetes, history of infection and malignancy, coagulation diseases Candidate patients for knee arthroscopy Absence of body mass index greater than 30 Absence of cardiovascular problems and arrhythmia Lack of psychological problems Absence of peripheral and central neuropathy Absence of local infection in the spinal area

Exclusion criteria:
The patient's lack of consent to continue participating in the study The patient's refusal to perform spinal anesthesia Failure to perform spinal anesthesia

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **140**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be allocated into 4 groups using a permuted balanced block randomization method with the size of blocks 4 and 8. Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (https://www.sealedenvelope.com/). Random chain concealment is done by opaque envelope method.

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to make the study double-blind, the data are measured, reviewed and recorded by an intern who is unaware of the groupings, and the preparation of drugs in each group is done by an anesthetist and used during surgery. The patient does not know about the grouping

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics comittee of Arak University of Medical Sciences

Street address
Ethics comittee, Research center, Payambar Azam complex, Basij squre ,Sardasht,Arak

City
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Province
Markazi

Postal code
3848176941

Approval date
2022-12-12, 1401/09/21

Ethics committee reference number
IR.ARAKMU.REC.1401.281

Health conditions studied

1

Description of health condition studied
knee arthroscopy

ICD-10 code
T84.042D

ICD-10 code description
Periprosthetic fracture around internal prosthetic right knee joint, subsequent encounter

Primary outcomes

1

Description
Pain

Timepoint
Recovery and 1, 6, 24 hours after surgery

Method of measurement
Visual Analogue Scale

2

Description
Average analgesic drug consumption

Timepoint
End of study

Method of measurement
Hospital file

Secondary outcomes

empty

Intervention groups

1

Description
. Intervention group 1: 100 milligeram magnesium sulfate without preservative (magnesium sulfate used will be 10% and manufactured by Pasteur Institute pharmaceutical company, Tehran-Iran) along with 15 milligeram bupivacaine 0.5% hyperbaric.
Category
Treatment - Drugs

2

Description
Intervention group 2: 8 millileter of 10% magnesium sulfate with 12 millileter of distilled water and a total volume of 20 millileter is administered intra-articularly.
Category
Treatment - Drugs

3

Description
Intervention group 3: 50 micrograms of fentanyl (manufactured by Caspian Tamin Company - Rasht, Iran) along with 15 mg bupivacaine 0.5% hyperbar (heavy) manufactured by Strazenka Company (Cambridge - England) imported by Kobel Daru Company (Tehran - Iran) will be.
Category
Treatment - Drugs

4

Description
Intervention group 4: 50 micrograms of fentanyl (manufactured by Caspian Tamin Company - Rasht, Iran) will be added to 19 ml of normal saline
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amiralmomenin hospital
Full name of responsible person
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Research Assistant of Arak University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Alireza Sosanabadi
Position
Assistant professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available