

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparison of addition of midazolam; fentanyl and magnesium sulfate to intrathecal bupivacaine on block characteristics and analgesia in knee arthroplasty

Protocol summary

Study aim

Comparison of addition of midazolam and fentanyl and magnesium sulfate to intrathecal bupivacaine on block characteristics and analgesia in knee arthroplasty

Design

The double blind randomized clinical trial, consisted of 105 patients who are randomly divided into 3 groups. The groups are parallel. The trial phase is 3.

Settings and conduct

The study population are patients with knee arthroplasty surgery in valiasr hospital in Arak who are divided into 3 groups by simple randomization using envelopes. The study is double-blind in which outcome evaluator, data analyst and participant are kept blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: being at the age of 18 to 60 years, ASA class 1 and 2, Patients who are candidates for knee replacement surgery. Non-inclusion criteria: The patient refuses to perform spinal anesthesia, failure to perform spinal anesthesia, local infection in the spinal part, peripheral and central neuropathy, mental health problems, arrhythmia.

Intervention groups

Intervention group1 : We will inject Midazolam at the dose of 2 milligram and hyperbar bupivacaine 0.5% at the dose of 15 milligram. Intervention group 2: We will inject Fentanyl at the dose of 50 micrograms with hyperbar bupivacaine 0.5% at the dose of 15 milligram. Intervention group3: We will inject magnesium sulfate at the dose of 100 milligram with hyperbar bupivacaine 0.5% at the dose of 15 milligram.

Main outcome variables

Duration of sensory block, duration of motor block, pain, mean analgesic drug, heart rate, blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N164**

Registration date: **2021-08-04, 1400/05/13**

Registration timing: **registered_while_recruiting**

Last update: **2021-08-04, 1400/05/13**

Update count: **0**

Registration date

2021-08-04, 1400/05/13

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-09, 1400/01/20

Expected recruitment end date

2022-03-11, 1400/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of addition of midazolam; fentanyl and magnesium sulfate to intrathecal bupivacaine on block characteristics and analgesia in knee arthroplasty

Public title

Effect of midazolam, fentanyl and magnesium sulfate to on analgesia in knee arthroplasty

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Being at the age of 18 to 60 years ASA class 1 and 2
Patients who are candidates for knee replacement surgery

Exclusion criteria:

The patient refuses to perform spinal anesthesia
Failure to perform spinal anesthesia
Local infection in the spinal part
Peripheral and central neuropathy
Mental health problems
Arrhythmia
Coagulation disorders
Cardiovascular problems

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization with random allocation with envelopes in 3 groups A and B and C. In this method, we selected a number of cards or letters as an intervention group and the same number of cards for the control group, then the cards were merged. One card was taken out and its allocation was registered and the card was returned to the other cards after leaving. Then the cards are merged again and we remove another card. This process continues to reach a random sequence according to sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is clinical trial. Outcome evaluator and analyzer and participant are blind (double blind). Outcome evaluator and analyzer and participant don't aware from grouping.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Ethics committee, Research center, Payambar Azam complex, Basij square, Sardasht

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2020-12-06, 1399/09/16

Ethics committee reference number

IR.ARAKMU.REC.1399.258

Health conditions studied

1

Description of health condition studied

Knee arthroplasty

ICD-10 code

Z96.65

ICD-10 code description

Presence of artificial knee joint

Primary outcomes

1

Description

Sensory block duration

Timepoint

After surgery

Method of measurement

Chronometer

2

Description

Motor block duration

Timepoint

After surgery

Method of measurement

Chronometer

3

Description

Pain

Timepoint

Recovery and 2, 4, 6, 12 and 24 hours after surgery

Method of measurement

Visual analog pain questionnaire

4

Description

Mean of opiate drug use

Timepoint

24 hours after surgery

Method of measurement

Milligram

5

Description

Mean blood pressure

Timepoint

Recovery and 2, 4 and 6 hours after surgery

Method of measurement

Sphygmomanometer

6

Description

Mean heart rate

Timepoint

Recovery and 2, 4 and 6 hours after surgery

Method of measurement

Count

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1 : We will inject Midazolam at the dose of 2 milligram and hyperbar bupivacaine 0.5% at the dose of 15 milligram.

Category

Treatment - Drugs

2

Description

Intervention group 2: We will inject Fentanyl at the dose of 50 micrograms with hyperbar bupivacaine 0.5% at the dose of 15 milligram.

Category

Treatment - Drugs

3

Description

Intervention group 3: We will inject magnesium sulfate at the dose of 100 milligram with hyperbar bupivacaine 0.5% at the dose of 15 milligram

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Dr Hesamodin Modir

Street address

Valiasr hospital, Valiasr square

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modir.he@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Arak University of Medical Sciences

Full name of responsible person

Dr Alireza Kamali

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Research Deputy, Payambar Azam Complex, Basij square, Sardasht

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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, 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 Esmaeel Moshiri

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Specialist

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Person responsible for updating data

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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