

# 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)

##### Phone

+98 86 3222 2003

##### Email address

f.farokhi@arakmu.ac.ir

##### 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

##### City

Arak

##### Province

Markazi

##### Postal code

3848176941

##### Phone

+98 86 3222 2003

##### Email

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

##### Street address

Research Deputy, Payambar Azam Complex, Basij square, Sardasht

##### City

Arak

##### Province

Markazi

##### Postal code

3848176941

##### Phone

+98 86 3222 2003

##### Fax

+98 86 3222 2003

##### Email

alikalaliir@yahoo.com

#### 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

**Street address**

Valiasr hospital; Valiasr square; Shahid Shirodi street

**City**

Arak

**Province**

Markazi

**Postal code**

3814957558

**Phone**

+98 86 3222 2003

**Fax**

+98 86 3222 2003

**Email**

modir.he@gmail.com

**Web page address**

**Postal code**

3814957558

**Phone**

+98 86 3222 2003

**Email**

modir.he@gmail.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Tayebe Sadat Sayafi Sharifi

**Position**

Medicine student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

Payambar Azam Complex, Basij square, Sardasht

**City**

Arak

**Province**

Markazi

**Postal code**

3814957558

**Phone**

+98 86 3222 2003

**Email**

he.modir@hotmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Hesamedin Modir

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Valiasr hospital; Valiasr square; Shahid Shirodi street

**City**

Arak

**Province**

Markazi

**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