

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Comparison of the effect of Midazolam, Dexamethasone, Ondansetron and Propofol in the prevention of opioid-induced pruritus after spinal anesthesia in femoral fracture surgery

#### Protocol summary

##### Study aim

Comparison of the effect of Midazolam, Dexamethasone, Ondansetron and Propofol in the prevention of opioid-induced pruritus after spinal anesthesia in femoral fracture surgery

##### Design

Double-blind clinical trial, 132 patients, 4 parallel groups by simple randomization. The trial phase is 3.

##### Settings and conduct

Patients candidate for hip fracture surgery at Valiasr hospital in Arak are divided into 4 groups by simple randomization with envelopes. The study is double-blind. Outcome evaluator and analyzer and participant are blind.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 65 years, ASA class 1 and 2, femoral fracture surgery, no history of any skin condition associated with generalized itching, no complaints of pruritus before surgery, no history of drug addiction, no history of seasonal allergies, no history of long-term corticosteroid use, absence of motion sickness, absence of diabetes, absence of neuromuscular diseases  
Exclusion criteria: Failure to anesthesia and use other methods, dissatisfaction.

##### Intervention groups

Intervention group 1: We inject 4 milligram Ondansetron bolus followed by 50 milliliter of distilled water with rate of 25 milliliter per hour. Intervention group 2: We inject 2 milligram Propofol bolus initially and then 10 micro grams per kilogram per minute (intravenous infusion drug is poured into 50 milliliter syringes). Intervention group 3: We inject 8 milligram Dexamethasone and then infuse 50 milliliter of distilled water with rate of 25 milliliter per hour. Intervention group 4: We inject 0.03 milligram Midazolam bolus and then infuse 0.02 milligram in kilogram in hours.

##### Main outcome variables

Itching, sedation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20141209020258N141**

Registration date: **2020-04-09, 1399/01/21**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-04-09, 1399/01/21**

Update count: **0**

##### Registration date

2020-04-09, 1399/01/21

##### 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

2020-02-20, 1398/12/01

##### Expected recruitment end date

2021-02-19, 1399/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Comparison of the effect of Midazolam, Dexamethasone, Ondansetron and Propofol in the prevention of opioid-induced pruritus after spinal anesthesia in femoral fracture surgery

### Public title

Management of opioid-induced pruritus after spinal anesthesia in femoral fracture surgery

### Purpose

Prevention

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Age 18 to 65 years ASA class 1 and 2 Femoral fractures surgery No history of any skin condition associated with generalized itching No complaints of pruritus before surgery No history of drug addiction No history of seasonal allergies No history of long-term corticosteroid use Absence of motion sickness Absence of diabetes Absence of neuromuscular diseases

#### Exclusion criteria:

Failure in the anesthesia and use another method  
Dissatisfaction

### Age

From **18 years** old to **65 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

### Sample size

Target sample size: **132**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Simple individual randomization with randomization with envelopes in 4 groups A and B and C and D . In this method, we write a few cards or letters as intervention groups and the same number of cards for the control group, then the cards are mixed. One card is taken out and its allocation is registered and the card is returned to the other cards after leaving. Then the cards are mixed again and then another card is picked up. This process continues to reach a random sequence according to sample size.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

This study is double blind. Outcome evaluator and analyzer and participant are blind. Outcome evaluator and analyzer and participant don't aware from grouping. Each group of drugs will be prescribed as a bolus and then intravenous infusion. Patients and outcome evaluator will be unaware of the prescribed medication. Bolus and infusion injection syringes as well as drug infusion sets will be covered with foil. After calculating the amount,

the required drugs are drawn in 50 ML syringes and prescribed at the desired dose.

### 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,Arak

##### City

Arak

##### Province

Markazi

##### Postal code

3848176941

#### Approval date

2020-02-09, 1398/11/20

#### Ethics committee reference number

IR.ARAKMU.REC.1398.313

## Health conditions studied

### 1

#### Description of health condition studied

Femoral fracture surgery

#### ICD-10 code

S72

#### ICD-10 code description

Fracture of femur

## Primary outcomes

### 1

#### Description

Itching

#### Timepoint

During recovery and up to 12 hours after surgery, every 2 hours

#### Method of measurement

Observation

### 2

#### Description

Sedation

#### Timepoint

Every 15 minutes until the end of surgery and in

recovery and then every 2 hours to 12 hours after surgery

**Method of measurement**

Ramsey score

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group1: We inject 4 milligram Ondansetron bolus followed by 50 millileter of distilled water with rate of 25 millileter per hour.

**Category**

Treatment - Drugs

**2****Description**

Intervention group 2: We inject 2 milligram Propofol bolus initially and then 10 micro grams per kilogram per minute (intravenous infusion drug is poured into 50 milliliter syringes).

**Category**

Treatment - Drugs

**3****Description**

Intervention group 3: We inject 8 milligram Dexamethasone and then infuse 50 milliliter of distilled water with rate of 25 milliliter per hour.

**Category**

Treatment - Drugs

**4****Description**

Intervention group 4: We inject 0.03 milligram Midazolam bolus and then infuse 0.02 milligram per kilogram per hours.

**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 squire

**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**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Alireza Kamali

**Street address**

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

**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**

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**  
Shahid Shirodi street, Valiasr square, Valiasr hospital  
**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**

## 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  
**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**  
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  
**Postal code**  
3814957558  
**Phone**  
+98 86 3222 2003  
**Email**  
modir.he@gmail.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

When we publish article in journal

### When the data will become available and for how long

After the article is published

### To whom data/document is available

Researcher in university

### Under which criteria data/document could be used

If there are additional questions

### From where data/document is obtainable

Dr Hesamedin Modir

### What processes are involved for a request to access data/document

They have to write letters to the professors and the university.

### Comments