

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

alikaliamaliir@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