

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### Comparison of the effect of addition of Ketamine, Lidocaine, Acetaminophen and Dexmedetomidine to morphine in the pain control of opium addicts after orthopedic surgery

#### Protocol summary

##### Study aim

Comparison of the effect of addition of ketamine, lidocaine and acetaminophen and dexmedetomidine to morphine in the pain control pump of opium addicts after orthopedic surgery

##### Design

The double blind clinical trial, consisting of 140 patients whom were randomly divided into 4 groups. The groups are parallel. The trial phase is 3.

##### Settings and conduct

Patients with opium addicts after orthopedic surgery at Valiasr hospital in Arak are divided into 4 groups by simple randomization with envelopes. The study is double-blind in which outcome evaluator and data analyst and participant are kept blind.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 20 to 60 years, ASA class 1 and 2  
Non inclusion criteria: Dissatisfaction with studying, not accepting spinal anesthesia as a method of anesthesia, obesity, chronic pain, mental disorders, history of seizures, psychotropic drugs, daily use of painkillers (more than a week), sensitivity to drugs, upper respiratory infection, pregnancy, breastfeeding, hemodynamic instability

##### Intervention groups

Intervention Group 1: 1 milligram/ kilogram of Ketamine (Rotex Medica, Germany) will be added to morphine .  
Intervention Group 2: 15 milligram/kilogram of Acetaminophen (Coble Drug - Iran) will be added to morphine.  
Intervention Group 3: 1/5 milligram/kilogram of Lidocaine(Caspian Tamin Rasht-Iran) will be added to morphine.  
Intervention Group 4:1 microgram/kilogram of Dexmedetomidine (Exir Company) will be added to morphine.

##### Main outcome variables

Relaxation; average drug use; nausea and vomiting; pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20141209020258N146**

Registration date: **2020-07-10, 1399/04/20**

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

Last update: **2020-07-10, 1399/04/20**

Update count: **0**

##### Registration date

2020-07-10, 1399/04/20

##### 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

2020-05-21, 1399/03/01

##### Expected recruitment end date

2021-05-22, 1400/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Comparison of the effect of addition of Ketamine, Lidocaine, Acetaminophen and Dexmedetomidine to morphine in the pain control of opium addicts after orthopedic surgery

### Public title

The effect of addition of ketamine, lidocaine and acetaminophen and dexmedetomidine to morphine in the pain control of opium addicts

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Age of 20 to 60 years old ASA class 1 and 2

#### Exclusion criteria:

Dissatisfaction with studying Not accepting spinal anesthesia as a method of anesthesia Obesity Chronic pain Mental disorders History of seizures Use psychotropic drugs Use of painkillers (more than a week) Sensitivity to drugs Upper respiratory infection Pregnancy Breastfeeding Existence of hemodynamic instability

### Age

From **20 years** old to **60 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

### Sample size

Target sample size: **140**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Simple individual randomization with envelopes into 4 groups of A and B and C and D . 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 mixed. 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 mixed again and we pulled out another card. This process continued 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 (double blind). Outcome evaluator and analyzer and participant don't aware from grouping. Drug 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; Vice Chancellor for Research and Technology; Payambar Azam complex, Basij square; Sardasht

##### City

Arak

##### Province

Markazi

##### Postal code

3848176941

#### Approval date

2020-05-10, 1399/02/21

#### Ethics committee reference number

IR.ARAKMU.REC.1399.060

## Health conditions studied

### 1

#### Description of health condition studied

Pain after orthopedic surgery

#### ICD-10 code

Z47.82

#### ICD-10 code description

Encounter for orthopedic aftercare following scoliosis surgery

## Primary outcomes

### 1

#### Description

Relaxation

#### Timepoint

At 1, 6, 12 and 24 hours after connecting the pump

#### Method of measurement

Ramsy score

### 2

#### Description

Average drug use

#### Timepoint

24 hours after connecting the pump

#### Method of measurement

Observation

### 3

**Description**

Nausea and vomiting

**Timepoint**

At 1, 6, 12 and 24 hours after connecting the pump

**Method of measurement**

Observation

### 4

**Description**

Pain

**Timepoint**

At 1, 6, 12 and 24 hours after connecting the pump

**Method of measurement**

Visual pain analog scale

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group 1: 1 mg/kg of Ketamine (produced by Rotex Medica company, Germany) will be added to morphine.

**Category**

Treatment - Drugs

### 2

**Description**

Intervention group 2: 15 mg/kg of Acetaminophen (produced by Coble Drug company, Iran) will be added to morphine.

**Category**

Treatment - Drugs

### 3

**Description**

Intervention group 3: 1.5 mg/kg of Lidocaine(produced by Caspian Tamin Rasht company-Iran) will be added to morphine.

**Category**

Treatment - Drugs

### 4

**Description**

Intervention group 4: 1 micro gram per kilogram of Dexmedetomidine (produced by Exir Company) will be added to morphine.

**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**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Alireza Kamali

**Street address**

Vice Chancellor for Research and Technology;  
Payambar Azam complex, Basij square; Sardasht

**City**

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**Province**

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**Phone**

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**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**

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****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Maryam Joshaghani

**Position**

Medicine student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

Vice Chancellor for Research and Technology;  
Payambar Azam complex, Basij square; Sardasht

**City**

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## 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, the raw data file will be provided to researchers.

**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 Hesamodin Modir

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

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

**Comments**

## 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

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modir.he@gmail.com

## Person responsible for updating data

### Contact