

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### Comparison of the effect of Dexmedetomidine, Granisetron and Ketamine on preventing post operative shivering after general anesthesia

#### Protocol summary

##### Study aim

Determination of the most effective drug among ketamine, dexmedetomidine and granisetron to prevent shivering after general anesthesia

##### Design

Triple-blind randomized clinical trial, with control group and parallel group design, with 4 groups

##### Settings and conduct

In this triple\_blind study, 148 patients candidates for laparoscopic cholecystectomy surgery under general anesthesia that referred to Arak's Valiasr Hospital will randomly be allocated into 4 equal groups. Each group receives one of these drugs: Dexmedetomidine, Granisetron, Ketamine, and placebo (normal saline). Patients, Clinical Caregiver and analyzer will be kept blind in this study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: being at the age of 18 to 65 years; ASA class 1 or 2; being candidate for abdominal laparoscopic surgery under general anesthesia; satisfaction with the study participation. Exclusion criteria: cardiovascular disease, kidney or endocrine disease, smoking and drugs, pregnancy

##### Intervention groups

Intervention group 1: Dexmedetomidine, Intervention group 2: Ketamine, Intervention group 3: Granisetron, control group: normal saline (placebo).

##### Main outcome variables

Post Anesthetic shivering; Body temperator

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191101045300N1**

Registration date: **2019-12-28, 1398/10/07**

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

Last update: **2019-12-28, 1398/10/07**

Update count: **0**

##### Registration date

2019-12-28, 1398/10/07

##### Registrant information

###### Name

Yazdan Shabani

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 3313 6055

###### Email address

yazdansh74@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-08-21, 1398/05/30

##### Expected recruitment end date

2020-03-19, 1398/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of Dexmedetomidine, Granisetron and Ketamine on preventing post operative shivering after general anesthesia

##### Public title

Comparison effect of Dexmedetomidine and Granisetron and ketamine to preventing post-operative complications

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Being at the age of 18 to 65 years old ASA class 1 or 2  
Patients candidate for abdominal laparoscopic surgery  
Satisfaction with study participation BMI<35

**Exclusion criteria:**

Being allergic to the prescribed medicines cardiovascular disease, kidney or endocrine disease smoking and addiction chronic Pulmonary Diseases (Asthma and COPD) pregnancy history of previous laparoscopy or previous laparotomy

**Age**

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

**Gender**

Both

**Phase**

1-2

**Groups that have been masked**

- Participant
- Care provider
- Data analyser

**Sample size**

Target sample size: **148**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random block allocation by statistical software.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

This study is triple-blind. The person responsible for recording patient's clinical signs in the recovery room, and the patients and the one who finally analyzes the results, all of them are not aware of used drug.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee Arak University Of Medical Sciences

**Street address**

Payambar Azam complex, Basij square, Sardasht, Arak

**City**

Arak

**Province**

Markazi

**Postal code**

38149578558

**Approval date**

2019-07-21, 1398/04/30

**Ethics committee reference number**

IR.ARAKMU.REC.1398.111

**Health conditions studied****1****Description of health condition studied**

Abnormal involuntary movements

**ICD-10 code**

T88.51

**ICD-10 code description**

Hypothermia following anesthesia

**Primary outcomes****1****Description**

Post Anesthetic shivering

**Timepoint**

0, 10, 20, 30, 40 and 50 minutes after entering to recovery room. 1, 2, 4 and 6 hours after entering to recovery room

**Method of measurement**

Quality Grading

**2****Description**

Body temperature

**Timepoint**

0, 10, 20, 30, 40 and 50 minutes after entering to recovery room. 1, 2, 4 and 6 hours after entering to recovery room

**Method of measurement**

Digital Thermometer

**Secondary outcomes**

empty

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

Intervention group 1: 0.5 mcg/kg of Dexmedetomidine will be injected intravenously 30 minutes before the end of the surgery

**Category**

Treatment - Drugs

**2****Description**

Intervention group 2: 0.5 mg/kg of Ketamine will be injected intravenously 30 minutes before the end of the surgery

**Category**

Treatment - Drugs

### 3

#### Description

Intervention group 3: 1.5 mg of Granisetron will be injected intravenously 30 minutes before the end of the surgery

#### Category

Treatment - Drugs

### 4

#### Description

Control group: 10 mg of normal saline will be injected intravenously 30 minutes before the end of the surgery.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Valiasr Hospital

##### Full name of responsible person

Dr Hesamodin Modir

##### Street address

Valiasr Hospital, Shahid Shirodi street, Arak

##### City

Arak

##### Province

Markazi

##### Postal code

411373671857

##### Phone

+98 86 3222 2003

##### Email

pr\_valieasr@arakmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Alireza Kamali

##### Street address

Arak University of Medical Sciences, Basij Square.,  
Arak

##### City

Arak

##### Province

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##### Postal code

3848176341

##### Phone

+98 86 3417 3639

##### Email

research@arakmu.ac.ir

##### 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 Hesamodin Modir

##### Position

Faculty member, Anesthesiologist

##### Latest degree

Specialist

##### Other areas of specialty/work

Anesthesiology

##### Street address

Valiasr Hospital, Valiasr square, Shahid Shirodi street.

##### City

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##### Province

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3814957558

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+98 86 3222 2003

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modir.he@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Dr Hesamodin Modir

##### Position

Faculty member, Anesthesiologist

##### Latest degree

Specialist

##### Other areas of specialty/work

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Dr Hesamodin Modir  
**Position**  
Faculty member, Anesthesiologist  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Anesthesiologist  
**Street address**  
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**Email**  
modir.he@gmail.com

## 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