

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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 temperatur

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

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411373671857

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

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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

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Dr Hesamodin Modir

Position

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Person responsible for updating data

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Name of organization / entity
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Full name of responsible person
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Position
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Latest degree
Specialist
Other areas of specialty/work
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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