

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### Comparison of the prophylactic effects of intravenous injection of Dexmedetomidine, Ondansetron, and pethidine on postoperative shivering of abdominal surgery under general anesthesia

#### Protocol summary

##### Study aim

Comparison of the prophylactic effects of intravenous injection of dexmedetomidine, Ondansetron, and pethidine on postoperative shivering.

##### Design

A randomized, controlled, double-blind, placebo-controlled clinical trial with a sample size of 128 patients was designed in a phase 3 trial.

##### Settings and conduct

This study is a double-blind randomized clinical trial that will be performed in the Alzahra hospital. The target population is patients undergoing abdominal surgery with general anesthesia. 128 patients will be selected having inclusion criteria and distributed by random allocation method in one of 4 groups. In each group, one of the dexmedetomidine, ondansetron, pethidine and distilled water too (as a placebo) is injected and at the end of the operation the patient is evaluated for postoperative shivering. The method of blinding is that patients are unaware of the type of drug they are given and also drugs will be provided in similar syringes and coded for those by a non-study operating room staff and given to the study expert to inject.

##### Participants/Inclusion and exclusion criteria

Patients who are the candidates for abdominal surgery under general anesthesia are included in this study if they have no underlying problem.

##### Intervention groups

In Group D: 0.5 µg /kg Dexmedetomidine in group O: 0.1 mg/kg Ondansetron in group P: 0.5 mg/kg Pethidine in group N: distilled water

##### Main outcome variables

shivering

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160307026950N18**

Registration date: **2020-04-01, 1399/01/13**

Registration timing: **prospective**

Last update: **2022-07-12, 1401/04/21**

Update count: **1**

##### Registration date

2020-04-01, 1399/01/13

##### Registrant information

###### Name

Behzad Nazemroaya

###### Name of organization / entity

Isfahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3212 3543

###### Email address

behzad\_nazem@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-09-22, 1399/07/01

##### Expected recruitment end date

2020-12-21, 1399/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the prophylactic effects of intravenous injection of Dexmedetomidine, Ondansetron, and pethidine on postoperative shivering of abdominal surgery under general anesthesia

#### Public title

The investigation of effects of dexmedetomidine, ondansetron and pethidin on postoperative shivering

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

ASA class I and II Candidate for abdominal surgery under general anesthesia The range from 18-60 years of age The patient's consent to participate in the study

##### Exclusion criteria:

A History of TCA, MAOI, vasoactive agent, painkiller and opiate medication Musculoskeletal and nervous system diseases, thyroid diseases Dysautonomia, fever, pregnancy, obesity(BMI>27) The history of cardiovascular, respiratory, endocrin or neurologic diseases Allergic to sulfate of magnesium, ketamine and pethidin

#### Age

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

#### Gender

Both

#### Phase

3

#### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

#### Sample size

Target sample size: **128**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Sampling will be done by the simple method and patients depending on the time of entry who meet the necessary conditions entered into the study in order to reach the sample size. Also, patients will be distributed in a randomized block allocation method and with the required number among the groups.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

The method of blinding is that patients are unaware of the type of drug they are given and also drugs and placebo provided in similar syringes and coded for those by the researcher and given to the study expert to inject. and the hemodynamic changes are monitored and recorded, so the attending and the clinical caregiver and the examiner and data analyzer will not understand the type of medication and the investigator deciphers the codes after data analysis.

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

###### Street address

Hezar Jerib street

###### City

Isfahan

###### Province

Isfahan

###### Postal code

81144-73441

##### Approval date

2019-06-30, 1398/04/09

##### Ethics committee reference number

IR.MUI.MED.REC.1398.182

### Health conditions studied

#### 1

##### Description of health condition studied

postoperative shivering

##### ICD-10 code

##### ICD-10 code description

### Primary outcomes

#### 1

##### Description

Shivering

##### Timepoint

On arrival to the recovery room and then every 15 minutes for one hour.

##### Method of measurement

Shivering severity is assessed by Crassly and Mahajan Score

#### 2

##### Description

Central temperature

##### Timepoint

Before surgery, before drug administration, after intubation, every 15 minutes during the anesthesia, at the end of anesthesia, after extubation, on arrival to the recovery room and then every 15 minutes for one hour

##### Method of measurement

Tympanic thermometer

### 3

**Description**

Peripheral temperature

**Timepoint**

Before surgery, before drug administration, after intubation, every 15 minutes during the anesthesia, at the end of anesthesia, after extubation, on arrival to the recovery room and then every 15 minutes for one hour

**Method of measurement**

Thermometer

### 4

**Description**

The level of sedation

**Timepoint**

At the base time; after the procedure and then every 15 minutes until discharge of recovery.

**Method of measurement**

Using the Ramsay Sedation Scale

### 5

**Description**

Severity of Pain

**Timepoint**

At the base time; after the procedure and then every 15 minutes until discharge of recovery.

**Method of measurement**

Using the Visual Analogue Scale

### 6

**Description**

Systolic blood pressure

**Timepoint**

Before surgery, every 15 minutes during the anesthesia, on arrival to the recovery room and then every 15 minutes

**Method of measurement**

Non invasive manometer

### 7

**Description**

Diastolic blood pressure

**Timepoint**

Before surgery, every 15 minutes during the anesthesia, on arrival to the recovery room and then every 15 minutes

**Method of measurement**

Non invasive manometer

### 8

**Description**

Oxygen saturation

**Timepoint**

since entering the operating room until leaving the recovery room

**Method of measurement**

Pulse oximeter

### 9

**Description**

Heart rate

**Timepoint**

since entering the operating room until leaving the recovery room

**Method of measurement**

Heart monitoring device

### 10

**Description**

Mean Arterial Blood Pressure

**Timepoint**

Before surgery, every 15 minutes during the anesthesia, on arrival to the recovery room and then every 15 minutes

**Method of measurement**

Non invasive blood pressure measurement

### 11

**Description**

Recovery length

**Timepoint**

On arrival to the recovery room and then every 15 minutes till recovery room

**Method of measurement**

Watch or clock

## Secondary outcomes

### 1

**Description**

Nausea

**Timepoint**

Recovery length

**Method of measurement**

Questioning

### 2

**Description**

Vomiting

**Timepoint**

Recovery length

**Method of measurement**

Observing

### 3

**Description**

Itching

**Timepoint**

Recovery length

**Method of measurement**

Questioning

### 4

**Description**

Atropine taken dose

#### **Timepoint**

Since the beginning of the operation until the end of the recovery length

#### **Method of measurement**

Asking from the anesthesia technician

### **5**

#### **Description**

Pethidine taken dose

#### **Timepoint**

Since the beginning of the operation until the end of the recovery length

#### **Method of measurement**

Asking from the anesthesia technician

### **6**

#### **Description**

Ephedrine taken dose

#### **Timepoint**

Since the beginning of the operation until the end of the recovery length

#### **Method of measurement**

Asking from the anesthesia technician

## **Intervention groups**

### **1**

#### **Description**

Intervention group D: First the written consent will be obtained from patients. after placing the patients on the bed, standard monitoring will be applied (including a pulse oximeter, capnograph, Manometer,ECG and basic vital signs ). for Group D: 0.5 µg /kg intravenous Dexmedetomidine will be injected after discontinuation the anesthetic drug, and mean arterial blood pressure, heart rate, systolic and diastolic blood pressure, and other variables are considered at the desired times.

#### **Category**

Prevention

### **2**

#### **Description**

Intervention group P: First the written consent will be obtained from patients. after placing the patients on the bed, standard monitoring devices will be applied (including a pulse oximeter, capnograph, Manometer,ECG and basic vital signs ). for group P: 0.5 mg/kg Pethidine will be injected after discontinuing the anesthetic drug, and mean arterial blood pressure, heart rate, systolic and diastolic blood pressure, and other variables are considered at the desired times.

#### **Category**

Prevention

### **3**

#### **Description**

Intervention group O: First the written consent will

beobtained from patients. after placing the patients on the bed, standard monitoring devices will be applied (including a pulse oximeter, capnograph, Manometer,ECG and basic vital signs ). for group O; 0.1 mg/kg Ondansetron will be injected after discontinuing the anesthetic drug, and mean arterial blood pressure, heart rate, systolic and diastolic blood pressure, and other variables are considered at the desired times.

#### **Category**

Prevention

### **4**

#### **Description**

Control group N; First the written consent will be obtained from patients. after placing the patients on the bed, standard monitoring devices will be applied (including a pulse oximeter, capnograph, Manometer,ECG and basic vital signs ). for group N, distilled wate will be injected after discontinuing the anesthetic drug, and mean arterial blood pressure, heart rate, systolic and diastolic blood pressure, and other variables are considered at the desired times.

#### **Category**

Placebo

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Alzahra hospital

##### **Full name of responsible person**

Behzad Nazemroaya

##### **Street address**

Soffeh boulevard, Shahid Keshvari highway

##### **City**

Isfahan

##### **Province**

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##### **Postal code**

8174675731

##### **Phone**

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##### **Email**

behzad\_nazem@med.mui.ac.ir

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Esfahan University of Medical Sciences

##### **Full name of responsible person**

Mahsa heydari

##### **Street address**

Esfahan University of Medical Sciences Hezar Ja rib Ave

##### **City**

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**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3668 0048

**Email**

research@mui.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Isfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mahsa Heydari

**Position**

Medical student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Behzad Nazemroaya

**Position**

Professor assistant of Anesthesia and Intensive care intensive care

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Leyla Rafiei

**Position**

Nurse Anesthesia

**Latest degree**

Bachelor

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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