Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 well 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)

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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 dexmedetomedine, 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, enocrin 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
Isfehan
Postal code
۸۱۷۴۶-۷۳۴۶۱
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

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mahsa heydari

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8174673461
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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
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Behzad Nazemroaya
Position
Professor assistant of Anesthesia and Intensive carentensive care
Latest degree
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Person responsible for updating data

Contact
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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