

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The prophylactic effect of intravenous injection of Dexmedetomidine, Ondansetron, Pethidine on tremor after abdominal surgery under the general anesthesia and comparison with control group

Protocol summary

Study aim

The prophylactic effect of intravenous injection of Dexmedetomidine, Ondansetron, Pethidine on tremor after abdominal surgery under the general anesthesia and comparison with control group

Design

A randomized, controlled, double-blind, placebo-controlled clinical trial

Settings and conduct

In a double blind clinical trial study in Alzahra and Kashani teaching hospitals in Isfahan, 128 patients undergoing abdominal surgery were divided into four groups of 32 patients and groups respectively of 0.5. Micrograms / kg dexmedetomidine, 0.5mg / kg pethidine, 0.1. Mg / kg ondansetron and normal saline were injected intravenously at the time of anesthesia and the incidence and severity of postoperative shivering were determined and compared in four groups. The method of blinding was that patients were unaware of the type of drug being administered, and the medication was prepared by one of the operating room staff who was not in the study, in similar, coded syringes, and was given expert advice on injection. .

Participants/Inclusion and exclusion criteria

Inclusion criteria: Male and female ASA-II candidates for abdominal surgery under general anesthesia in the age range of 18 to 60 years. Exclusion: TCA, MAOI, vasoactive, pain medication history, Opioid, Nerve and Muscle Disease, Thyroid Disease, Dys autonomic, Fever, A history of cardiovascular, respiratory, endocrine Or neurological, BMI>27 , obesity, pregnancy , hypersensitivity to magnesium sulfate, ketamine and pethidine drugs.

Intervention groups

128 patients who met the inclusion criteria were enrolled They were studied and randomly assigned to one of these four groups, respectively Will take. In group D, 0.5

µg / kg dexmedetomidine - in group P 0.5 mg / kg pethidine - in group O, one tenth mg / kg ondansetron - in group N, distilled water is also volumeized in similar syringes.

Main outcome variables

Prevention of shivering after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190708044155N1**

Registration date: **2019-08-25, 1398/06/03**

Registration timing: **registered_while_recruiting**

Last update: **2019-08-25, 1398/06/03**

Update count: **0**

Registration date

2019-08-25, 1398/06/03

Registrant information

Name

Mahsa Heydari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3258 0119

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-30, 1398/04/09

Expected recruitment end date

2019-09-22, 1398/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The prophylactic effect of intravenous injection of Dexmedetomidine, Ondansetrone, Pethidine on tremor after abdominal surgery under the general anesthesia and comparison with control group

Public title
The effect of Dexmedetomidine, Ondansetrone, Pethidine on tremor after abdominal surgery

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Men and women with ASA 1 and 2 Candidate for abdominal surgery under general anesthesia 18 to 60 years old
Exclusion criteria:
History of Vasoactive Drugs, Opioids, TCA, MAOI Nerve and muscle disease Thyroid disease Fever Pregnancy Obesity BMI> 27 Cardiovascular, Respiratory, Endocrine, Neurological diseases Sensitivity to Pethidine, Ondansetrone, Ketamine

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **128**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are randomly assigned to intervention and control groups with using the Random Allocation computer software.

Blinding (investigator's opinion)
Double blinded

Blinding description
The drugs and placebo are prepared in one form and in the form of a volume in the syringe by the researcher and the hemodynamic changes created are monitored and recorded. Therefore, the participant and the clinical caregiver and evaluator and data analyser analyst do not understand the type of drug and after analyzing the codes by the researcher Decoded.

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 jarib street
City
Isfahan
Province
Isfahan
Postal code
81774673461
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
Tremor rate after surgery

ICD-10 code
R25.1

ICD-10 code description
Tremor, unspecified

Primary outcomes

1

Description
Tremor rate after surgery

Timepoint
For the first 15 minutes continuously and then every 15 minutes to 1 hour

Method of measurement
Crassly and Mahajan

Secondary outcomes
empty

Intervention groups

1

Description

Intervention 1: In group D 0.5mg / kg dexmedetomidine - injected intravenously 1 time after the last wound is closed

Category

Prevention

2

Description

Intervention group 2: In group P 0.5mg / kg pethidine - injected intravenously 1 time after the last wound is closed

Category

Prevention

3

Description

Intervention group 3 in group O One tenth mg / kg ondansetron -injected intravenously 1 time after the last wound is closed

Category

Prevention

4

Description

In control group 1: In group N distilled water in syringe Similar volumes are also generated. All cases are volumeized 1 time and are injected intravenously 1 time after the last wound is closed

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Behzad Nazemroaya

Street address

Hizar jirib street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooy Javanmard

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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

Esfahan 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

Student of medicine

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

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Full name of responsible person

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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

Medical doctor

Other areas of specialty/work

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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

Information about the main outcome is published.

When the data will become available and for how long

3 months after printing the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

For information on continuing research

From where data/document is obtainable

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Mahsa Heidari-Isfahan University of Medical Sciences

behzad_nazem@md.mui.ac.ir 00989162907797 Dr.

Behzad Nazem Raaya-Al-Zahra Hospital

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

Email your request.

Comments