Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

The effect of preoperative intravenous ondansetrone for prevention of postoperative shivering in patients undergoing gynecologic surgeries with remifentanil-propofol anesthesia

Protocol summary

Study aim

Prevention of intra and post spinal shivering in cesarean section

Design

This study is a clinical trial study with control group with parallel, double blind and randomized groups.100 women undergoing elective surgery who referred to al-Zahra hospital for surgery Will be examined.The study has two groups of 50 intervention and control group,in the intervention group, 50 women will receive 8 mg Ondansetron and the control group consisted of 50 women who received the same amount of intravenous normal saline .

Settings and conduct

In this study, patients, clinical caregivers, and data analyzers will not aware of grouping.100 women undergoing elective surgery who referred to al-Zahra hospital for surgery Will be examined.The study has two groups of 50 intervention and control group,in the intervention group, 50 women will receive 8 mg Ondansetron and the control group consisted of 50 women who received the same amount of intravenous normal saline and patient's shivering will be examined within 30 minutes in the recovery.Using four scales, the patient's shivering will be assessed .All scales will be treated primarily with warm Baptos and if shivering is sustained, pethidine will be treated.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Patients with American Society of Anesthesiology (ASA) physical status I or II Exclusion criteria : Patients with ASA class III or higher ; Patients with cardiopulmonary diseases ; Preoperative fever; Age range under 25 and over 70 years; Addicted patients.

Intervention groups

Intervention group: 8 mg ondansetron will be injected before anesthesia begins. Control group:8 mg normal saline will be injected intravenously before the anesthesia begins.

Main outcome variables

Vital Signs(blood pressure, heart rate) Arterial blood oxygen saturation Need for pethidine shivering Any potential complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121209011700N10**
Registration date: **2019-10-21, 1398/07/29**
Registration timing: **registered_while_recruiting**

Last update: **2019-10-21, 1398/07/29**
Update count: **0**

Registration date

2019-10-21, 1398/07/29

Registrant information

Name

Farnaz Moslemi Tabrizi

Name of organization / entity

Alzahra hospital, Tabriz university of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1553 9161

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of preoperative intravenous ondansetrone for prevention of postoperative shivering in patients undergoing gynecologic surgeries with remifentanil-propofol anesthesia

Public title

The effect of ondansetrone for prevention of shivering

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with American Society of Anesthesiology (ASA) physical status I or II

Exclusion criteria:

Patients with ASA class III or higher Patients with cardiopulmonary diseases Preoperative fever Use of any anti pyretic or anti-inflammatory medication Age range under 25 and over 70 years Addicted patients

Age

From **25 years** old to **70 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Care provider
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

We will construct 6 blocks in AABB, BBAA, ABAB, BABA, ABBA and BAAB using four blocks. We will assign 1 to 6 for each block. Then, using the random number table, based on the sample size, 25 units of 4 blocks will be selected so that we consider having 50 people in control group (A) and 50 people in intervention group (B). Therefore, we will do block randomization.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients, clinical caregivers, and data analyzers will not aware of grouping.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Vice chancellor for research, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5183915881

Approval date

2019-08-19, 1398/05/28

Ethics committee reference number

IR.TBZMED.REC.1398.571

Health conditions studied

1

Description of health condition studied

Postoperative shivering

ICD-10 code

R68.0

ICD-10 code description

Hypothermia, not associated with low environmental temperature

Primary outcomes

1

Description

Shivering due to anesthesia

Timepoint

immediate after the intervention, after 5 minute, after 10 minute, after 20 minute, after 30 minute, ...

Method of measurement

PAS(five point rating scale)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 8 mg ondansetron will be injected before anesthesia begins.

Category

Prevention

2

Description
Control group:8 mg normal saline will be injected intravenously before the anesthesia begins.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
Dr .Farnaz Moslemi
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Al-Zahra Hospital ,Sought Artesh Street, Tabriz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr.Joyban
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Vice chancellor for research, Daneshgah Street, Tabriz
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research-vice@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Dr .Farnaz Moslemi
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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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
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
all collected deidentified IPD, IPD collected for the primary outcome measure are to be shared

When the data will become available and for how long
starting 6 months after publication

To whom data/document is available
documents will be available for people working in academic institutions and also people working in businesses.

Under which criteria data/document could be used
There will be no specific limitations to the utilization of the data

From where data/document is obtainable
Dr .Seyed Hadi Saghaleini Sina Hospital Azadi Street, Sina Hospital, Tabriz East Azarbaijan Islamic Republic of Iran Phone+98 41 35412101 Fax+98 41 35412101 hsaghaleini@gmail.com

What processes are involved for a request to access data/document
Correspondence through email only

Comments