

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

A Comparative Study of Granisetron and Ondansetron and ptedin for Prevention of Postoperative Shivering: A Randomized Clinical Trial

Protocol summary

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Summary

The aim of this study is to compare the effect of Granisetron, Ondansetron and pethidine in the prevention of shivering surgery. In this double-blind clinical trial, 120 patients candidated for surgery (General, Orthopedic and ENT surgeries) under general anesthesia in Ardabil Imam Khomeini Hospital will be enrolled after signing informed consent. The patients will be randomly assigned to receive normal saline 2 ml, pethidine 25 mg, Ondansetron 4 mg, Granisetron 40 µg/kg after induction of general anesthesia with the same method. The incidence of shivering and its severity will be recorded by a trained nurse, who is blind regarding the intervention, in the recovery.

Recruitment status

Recruitment complete

Funding source

Ardabil University of Medical Sciences

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2013-06-21, 1392/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204284093N4**

Registration date: **2012-05-25, 1391/03/05**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-05-25, 1391/03/05

Registrant information

Name

Masood Entezariasl

Name of organization / entity

Ardabil University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

Scientific title

A Comparative Study of Granisetron and Ondansetron and ptedin for Prevention of Postoperative Shivering: A Randomized Clinical Trial

Public title

A Comparative Study of Granisetron and Ondansetron and ptedin for Prevention of Postoperative Shivering: A Randomized Clinical Trial

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Candidate for surgery (General, Orthopedic and ENT surgeries), general anesthesia, ASA class I-II Exclusion criteria: history of substance abuse, presence of neuromuscular diseases, hypersensitivity to the study drugs, evidence of grade 3 or 4 of heart failure, fever (more than 37/8 ° orally), history of alpha2-receptor antagonist drugs consumption

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 120

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ardabil University of Medical Sciences

Street address

Ardabil University of Medical Sciences

City

Ardabi

Postal code

Approval date

2012-03-14, 1390/12/24

Ethics committee reference number

904/1

Health conditions studied

1

Description of health condition studied

shivering

ICD-10 code

R 68.8

ICD-10 code description

Other specified general symptoms and signs

Primary outcomes

1

Description

postoperative shivering

Timepoint

After surgery in recovery room

Method of measurement

Visual analog scale of chills

Secondary outcomes

1

Description

Central and peripheral temperature

Timepoint

Before the intervention, during surgery, in the recovery room after surgery

Method of measurement

Tympanic and environmental Thermometer

Intervention groups

1

Description

Granisetron(40cg//kg, increased volume to 2 ml) before induction of anesthesia

Category

Prevention

2

Description

Ondansetron(4mg, increased volume to 2 ml) before induction of anesthesia

Category

Prevention

3

Description

Pethidine (25 mg, increased volume to 2 ml) before induction of anesthesia

Category

Prevention

4

Description

Normal Saline, 2 ml, before induction of anesthesia

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Dr Masood Entezariasl

Street address

City

Ardabil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Dr Akbar Pirzadeh

Street address

Ardabil University of Medical Sciences

City

Ardabil

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ardabil University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Dr Masood Entezariasl

Position

Associate Professor of Anesthesiology

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty