

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

comparison of ondansetron and meperidine in treatment of postanesthetic shivering in patients under laparotomy surgeries with general anesthesia

Protocol summary

Summary

Comparison of effects of ondansetron and meperidine on postanesthesia shivering treatment is the goal of this study. inclusion criteria are ASA I,II patients with postanesthesia shivering after laparotomy surgeries, no response to surface warming, shivering score more than 1. Exclusion criteria are age less than 20 and more than 60 years old, hepatic disease, drug allergic reactions, history of prolonged QT syndrome in relatives, history of pulmonary disease, convulsion, allergy to narcotics, consumption of Tricyclic Antidepressants or Monoamine oxidase inhibitors, elevated Intracranial Pressure, severe renal disease, hypothyroidism, narcotic drug addiction. Population of study is the patients with postanesthesia shivering in recovery room of Firoozgar hospital. Total sample size is 40 and the trial is double blinded. Drug intervention is injection of 8 milligram ondansetron intravenously or 25 milligram meperidine intravenously in recovery room to control postoperative shivering. Final aim of the study is to define the success rate of ondansetron in treatment of shivering and comparison of the time to end shivering between 2 drugs.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109224969N3**
Registration date: **2012-01-11, 1390/10/21**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-01-11, 1390/10/21

Registrant information

Name

Alireza Pournajafian

Name of organization / entity

Tehran University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Science

Expected recruitment start date

2011-11-01, 1390/08/10

Expected recruitment end date

2012-04-29, 1391/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of ondansetron and meperidine in treatment of postanesthetic shivering in patients under laparotomy surgeries with general anesthesia

Public title

comparison of ondansetron and meperidine in treatment of postanesthetic shivering in patients under laparotomy surgeries with general anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria : ASA I,II patients between with postoperative shivering; no respons to surface warming; shivering score more than 1 exclusion criteria: age less than 20 and more than 60 y. Contraindication of Ondansetron; hepatic disease; drug allergic reactions; history of prolonged QT syndrom in relatives; contraindication of meperidin; history of pulmonary disease; convulsion; allergy to narcotics; consumption of Tricyclic Antidepressants or Mono Amino Oxydase Inhibitors; elevated Intracranial Pressure; sever renal disease; hypothyroidism; narcotic drug addiction.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Science

Street address

Ghods st.- Keshavarz blvd.

City

Tehran

Postal code

Approval date

2011-12-26, 1390/10/05

Ethics committee reference number

42887-12966-30-03-90

Health conditions studied

1

Description of health condition studied

Post anesthesia shivering

ICD-10 code

T88.5

ICD-10 code description

Hypothermia following anaesthesia

Primary outcomes

1

Description

control of postanesthesia shivering

Timepoint

after 10 minutes

Method of measurement

shivering score (1-4)

Secondary outcomes

1

Description

exact time of ending of shivering

Timepoint

every 1 minutes until minute 10

Method of measurement

shivering score(1 to 4)

Intervention groups

1

Description

intravenous injection of 25 milligram meperidine

Category

Treatment - Drugs

2

Description

intravenous injection of 8 milligram Ondansetron

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar hospital

Full name of responsible person

Alireza Pournajafian

Street address

Beh Afarin st. Karim Khan blvd.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Science

Full name of responsible person

Shohreh Asadi

Street address

Poursina st.- Keshavarz blvd.

City

Tehran

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

Yes

Title of funding source

Tehran University of Medical Science

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

Tehran University of Medical Science

Full name of responsible person

Alireza Pournajafian

Position

Assistant Professor of Anesthesia

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Full name of responsible person

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Position

Assistant Professor of Anesthesia

Other areas of specialty/work**Street address**

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Web page address**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*