

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of ondansetron and meperidine for prevention of postoperative shivering in patients undergoing General Anesthesia for lower extremity surgery

Protocol summary

Summary

purpose: The purpose of this double blinded study was Comparison of ondansetron and meperidine for prevention of PAS in patients undergoing GA for lower extremity surgery. Methods In this clinical trial, 105 patients with the age of 20-60 y/o and ASA class I, II, III were scheduled for elective orthopedic lower extremity surgery divided randomly assigned to one of three groups: intervention: M (meperidine), O (ondansetron), C (saline) After received premedication and immediately before the induction of anaesthesia; Sao₂ recorded by pulse oxymeter. In first group, 25mg Meperidine IV and in second group, 4mg Ondansetron IV and in third group (control), 2ml saline IV were administered immediately before the induction. GA in all patients induced equivalently with similar drugs and methods. All patients immediately after emergence of GA and extubation transported to recovery room (PACU). In the times of 5 and 15 minutes after the entrance to recovery room, Sao₂ (by pulse oxymeter measurement) and shivering were assessed and recorded by nurse who was unaware of research methods. PAS control was graded with Wernch et al. system (0 = no shivering, 1 = muscle activity in only one muscle group, 2 = muscle activity in more than one muscle group, 3 = shivering involving the whole body). Primary outcome measure: post operative chills Primary outcome time point: twice (between five - fifteen min) Primary outcome method of measurement: four point scale Inclusion: Graps Triminol; 20-60 years old Inclusion criteria: Graps Triminol; ASA class 1, 2, 3; Undergoing general anesthesia for lower extremity surgery exclusion criteria: Cardiovascular disease, psychiatric dis, thyroid dis, drug allergic reaction - body temperature ≥ 38 or ≤ 36.3 °C - DM - obesity - procedures which require administration of blood and blood products & anticipated duration more than 180

min.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106096758N1**

Registration date: **2011-08-13, 1390/05/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-08-13, 1390/05/22

Registrant information

Name

Mohammad Ghasem Roshanfekr Balalemi

Name of organization / entity

Qazvin, University Of Medical and Health Science

Country

Iran (Islamic Republic of)

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+98 28 1333 6002

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research, qazvin university of medical sciences and health services

Expected recruitment start date

2010-10-23, 1389/08/01

Expected recruitment end date

2011-02-20, 1389/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of ondansetron and meperidine for prevention of postoperative shivering in patients undergoing General Anesthesia for lower extremity surgery

Public title

Comparison of ondansetron and meperidine for prevention of postoperative shivering

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion: Graps Triminol ;20-60years old ;Asa class 1,2,3 ;Under going general anesthesia for lower extremity surgery exclusion:Cardiovascular disease ,psychiatric dis, thyroid dis, drug allergic reaction - body temperature ≥ 38 or ≤ 36.3 ° c - DM - obesity - procedures which require administration of blood and blood products & anticipated duration more than 180 min.

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: **105**

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**

Qazvin universityof medical sciences

Street address

Shahid Bahonar Blvd

City

Qazvin

Postal code**Approval date**

2010-03-20, 1388/12/29

Ethics committee reference number

28/20/4436

Health conditions studied**1****Description of health condition studied**

Diseases of the nervous system

ICD-10 code

G90

ICD-10 code description

Disorders of autonomic nervous system

Primary outcomes**1****Description**

post operative cheels

Timepoint

Twice(between 5-15min)

Method of measurement

4 point scale

Secondary outcomes**1****Description**

sao2

Timepoint

-

Method of measurement

between 1-100

Intervention groups**1****Description**

Intervention: :M(meperidine) 25mg /IV imediately before of induction .

Category

Prevention

2**Description**

Intervention: O(ondansetron) 4mg /IV imediately before of induction

Category

Prevention

3**Description**

Control: C(saline) 2mg /IV

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shaid Rajee Hospital

Full name of responsible person

Dr Mohamad ghasem roshanfekr balalemi

Street address

Padeghan Street

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

vice-chancellor for research of Qazvin universityof
medical science

Full name of responsible person

Dr Saeed Assefzadeh

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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

vice-chancellor for research of Qazvin universityof
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

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr Mohamad Ghasem Roshanferkr Balalemi

Position

Assitant resident

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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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