

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Granisetron in prevention of shivering after spinal anesthesia in lower Abdominal Surgery

Protocol summary

Summary

The aim of this study is to determine the effect of granisetron in prevention of post spinal anesthesia shivering. In a randomized clinical trial 105 patients with age 18-60 yr and American society of anesthesia (ASA) class 1-2 who have undergo in lower abdominal surgery randomly allocate in three groups. Group A receive 1 mg intravenous granisetron, group B 3 mg intravenous granisetron and group C five ml normal saline intravenously. Before induction of spinal anesthesia, the prepared solutions will be administered intravenously. Same spinal anesthesia at L2-L3 or L3-L4 level will be used in all patients. Bupivacain 0.5% with dose 10-14 mg will be used. No sedative or narcotic will be use after spinal anesthesia. During surgery and recovery, patients will be monitored for shivering, pain, hemodynamic alteration and other complications. During surgery and at post operative care unit, patients will be covered. Oxygen will be administered by face mask for all patients and they will be monitored. Anesthesiologist who is not aware about patients groups, will record the shivering, nausea, vomiting and pain. In addition, any other complications such as hemodynamic alteration will be record. In addition to oxygen therapy, patients with shivering will be warmed. In patients who have shivering with grade 3 or more , petidine (25 mg IV) every 20 minute in maximum three doses will be used

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201411203915N14**
Registration date: **2014-12-09, 1393/09/18**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-12-09, 1393/09/18

Registrant information

Name

Manizheh Mostafa Gharehbaghi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1526 2253

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Granisetron in prevention of shivering after spinal anesthesia in lower Abdominal Surgery

Public title

Effect of Granisetron in prevention of shivering after spinal anesthesia in lower Abdominal Surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: ages 18-60 yr; American society of

anesthesia (ASA) class 1-2; elective inguinal hernia repair with spinal anesthesia. Exclusion criteria: patients refuse of spinal anesthesia; any contraindication for regional anesthesia.

Age

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

Gender

Both

Phase

2-3

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

Ethic Committee of Tabriz University of Medical Sciences

Street address

Golgasht street

City

Tabriz

Postal code

Approval date

2014-03-10, 1392/12/19

Ethics committee reference number

9384

Health conditions studied

1

Description of health condition studied

Shivering after regional anesthesia

ICD-10 code

Y40-Y84

ICD-10 code description

Complications of medical and surgical care

Primary outcomes

1

Description

Post-operative shivering

Timepoint

Till 2 hours after surgery

Method of measurement

Clinical assessment

Secondary outcomes

1

Description

Need for petidine administration

Timepoint

Till 2 hours after surgery

Method of measurement

Clinical assessment

Intervention groups

1

Description

Group A : Administration of intravenous granisetron 1mg before spinal anesthesia

Category

Treatment - Drugs

2

Description

Group B: Administration of intravenous granisetron 3 mg before spinal anesthesia

Category

Treatment - Drugs

3

Description

group C: Administration of intravenous saline normal 5 ml before spinal anesthesia

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Dr Ali Peirovifar

Street address

Golgasht Street

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Vice Chancellor for Tabriz University of Medical Sciences

Full name of responsible person

Dr Farhoodi

Street address

Golgasht street

City

Tabriz

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

Yes

Title of funding source

Research Vice Chancellor for Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

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Position

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Web page address

Person responsible for updating data

Contact

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