Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 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 granisetrone 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 granisetrone, group B 3 mg intravenous granisetrone 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
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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 intavenous granisetrone 1mg before spinal anesthesia

Category
Treatment - Drugs

2

Description
Group B: Administration of intravenous granisetrone 3 mg befor 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

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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

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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