

# 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

###### Email address

peirovifara@tbzmed.ac.ir

##### 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**

Dr Ali Peirovifar

**Position**

Associate Professor

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

Operation room, Emam Reza hospital, Golgasht street

**City**

Tabriz

**Postal code****Phone**

+98 41 3334 7054

**Fax****Email**

peirovifara@gmail.com

**Web page address**

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr Abasali Dehghani

**Position**

Associate professor

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

Operation room, Emam Reza hospital, Golgasht street

**City**

Tabriz

**Postal code****Phone**

+98 41 3334 7054

**Fax****Email**

dehghania@tbzmed.ac.ir

**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*