

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### The effect of Intrathecal Atropine to prevent Nausea & Vomiting after surgeries due to use Intrathecal Morphine in lower limb surgeries

#### Protocol summary

##### Summary

Objective: The effect of Intrathecal Atropine to prevent Nausea & Vomiting after surgeries due to use Intrathecal Morphine in lower limb surgeries Design: Randomized; Double blind; Placebo; Single center Participants including major eligibility criteria: The patients aged from 40-70 years Participants excluding major eligibility criteria: Patients with history Neurologic disease and Neuromuscular; Diabetes Mellitus; Patients with Neuropathy Peripheral; Infection in site of injection; Sensitivity to Local Anesthesia; Patients with Vomiting and Nausea before surgery or receiving 48 hours before surgery Anti Vomiting and Nausea; Women in period of mense 120 patients Intervention: Intrathecal Atropine Setting and conduct: Patients divided into 2 groups by random allocation, A and B; Spinal Anesthesia performed for each group with 2.5cc Hyperbaric Bupivacaine 0.5% and 0.2mg (1cc) Intrathecal Morphine. Patients received 0.1mg (1cc) Intrathecal Atropine in group A and 1cc Normal-Saline 0.9%. Then on the basis of provided check-list, The Nausea & Vomiting checked during 24 hours after surgery (every 1 hour for 6 hours after surgery, Then during 6 hours and 12 hours after surgery). The Heart Rate and Blood Pressure changes checked at 3, 5, 10 and 15 minutes after performing Intrathecal Atropine. In this study, The Rate of Analgesia surveyed for 12 hours every 2 hours. Variables of main outcome: Incidence of Vomiting and Nausea for each group.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013012012204N1**

Registration date: **2013-12-09, 1392/09/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-12-09, 1392/09/18

##### Registrant information

###### Name

Fatemeh Shima Hadipourzadeh

###### Name of organization / entity

Qazvin University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 28 1336 5054

###### Email address

fhadipourzade@qums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Qazvin University of Medical Sciences

##### Expected recruitment start date

2013-03-05, 1391/12/15

##### Expected recruitment end date

2013-08-21, 1392/05/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of Intrathecal Atropine to prevent Nausea & Vomiting after surgeries due to use Intrathecal Morphine in lower limb surgeries

##### Public title

The effect of Intrathecal Atropine to prevent Nausea & Vomiting after surgeries due to use Intrathecal Morphine

in lower limb surgeries

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

Participants including major eligibility criteria: The patients aged from 40-70 years  
Participants excluding major eligibility criteria: Patients with history Neurologic disease and Neuromuscular; Diabetes Mellitus; Patients with Neuropathy Peripheral; Infection in site of injection; Sensitivity to Local Anesthesia; Patients with Vomiting and Nausea before surgery or receiving 48 hours before surgery  
Anti Vomiting and Nausea; Women in period of mense

### **Age**

From **40 years** old to **70 years** old

### **Gender**

Both

### **Phase**

2-3

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **120**

### **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**

Ethics Comitia Qazvin University of Medical Sciences

##### **Street address**

Qazvin University of Medical Sciences, Navab Street, Qazvin

##### **City**

Qazvin

##### **Postal code**

#### **Approval date**

2013-02-27, 1391/12/09

#### **Ethics committee reference number**

28/20/7034

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Spinal Anesthesia

#### **ICD-10 code**

T41.3

#### **ICD-10 code description**

local anaesthetics

## **Primary outcomes**

### 1

#### **Description**

Incidence of Vomiting and Nausea

#### **Timepoint**

Incidence of Nausea and Vomiting were studied in patients within 24 hours after injection of Atropine: Hourly up to 6 hours, Then 6 hours later and Finally 12 hours later.

#### **Method of measurement**

With checklist: Mild; Moderate; Severe

## **Secondary outcomes**

### 1

#### **Description**

Heart Rate

#### **Timepoint**

3,5,10,15 Minutes after Spinal Anesthesia with receiving Atropin Interathecal

#### **Method of measurement**

Heart Rate per minute

### 2

#### **Description**

Blood Pressure

#### **Timepoint**

3,5,10,15 Minutes after Spinal Anesthesia with receiving Atropin Intrathecal

#### **Method of measurement**

Blood volume pump by heart

### 3

#### **Description**

With out pain period

#### **Timepoint**

Intrathecal Morphine-Induced Analgesia was studied in 2 hours intervals for 12 hours after injection.

#### **Method of measurement**

With checklist

## **Intervention groups**

### 1

#### **Description**

GroupB Spinal Anesthesia was induced using 2.5 cc of 0.5 % Hyperbaric Bupivacaine and 0.2 mg (1cc) of

Intrathecal Morphine. In addition patients in group B received 1cc of saline 0.9%.

**Category**

Placebo

**2**

**Description**

Group A Spinal Anesthesia was induced using 2.5 cc of 0.5 % Hyperbaric Bupivacaine and 0.2 mg (1cc) of Intrathecal Morphine. In addition patients in groupA received 0.1 mg (1cc) Intrathecal Atropine

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Shahid Rajaee Hospital

**Full name of responsible person**

Fatemeh Shima Hadipourzadeh

**Street address**

Shahid Rajaee Hospital, Padegan Street, Qazvin

**City**

Qazvin

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice chancellor for research, Qazvin University of Medical Sciences

**Full name of responsible person**

Mahnaz Abaci

**Street address**

Qazvin University of Medical Sciences, Navab Street, Qazvin

**City**

Qazvin

**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, Qazvin 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**

Qazvin University of Medical Sciences

**Full name of responsible person**

Fatemeh Shima Hadipourzadeh

**Position**

Resident Anesthesia

**Other areas of specialty/work**

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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*