Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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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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Position

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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