

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

A clinical trial to comparison the effectiveness of oral Tizanidine and placebo on duration of sensory block and hemodynamic changes in patients undergoing limb orthopedic surgery under spinal anesthesia

Protocol summary

Summary

Objective: To compare the effectiveness of oral Tizanidine and placebo on duration of sensory block and hemodynamic changes in patients undergoing limb orthopedic surgery under spinal anesthesia. Design: A single-blinded, block randomized clinical trial. Study population: Patients are undergoing limb orthopedic surgery under spinal anesthesia. Inclusion criteria: Aged between 18 and 60 years; ASA I or II scheduled for limb orthopedic surgery under spinal anesthesia. Exclusion criteria: History of high blood pressure; history of uncontrolled diabetes; history of cardiovascular disease; history of renal failure; history of cirrhosis; history of smoking or drug abuse; patients with paresthesia higher levels of T4. Sample size: 70 cases. Study intervention: The control group are revising 4 mg of placebo 90 minutes before spinal anesthesia, intervention group are revising 4 mg of oral Tizanidine 90 minutes before spinal anesthesia. Study outcome: Duration of sensory block is measuring each 15 minutes after spinal anesthesia by pin prick method. Blood pressure and heart rate are measuring before and 5, 10, 15, 30, 60 and 90 minutes after spinal anesthesia by monitoring.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201610104780N10**
Registration date: **2016-10-21, 1395/07/30**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-10-21, 1395/07/30

Registrant information

Name

Mohammad Alipour

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1801 2612

Email address

alipourm@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Mashhad University of Medical Sciences

Expected recruitment start date

2016-10-31, 1395/08/10

Expected recruitment end date

2017-11-01, 1396/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to comparison the effectiveness of oral Tizanidine and placebo on duration of sensory block and hemodynamic changes in patients undergoing limb orthopedic surgery under spinal anesthesia

Public title

The effectiveness of oral Tizanidine on duration of sensory block in patients undergoing surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Aged between 18 and 60 years; ASA I or II scheduled for limb orthopedic surgery under spinal anesthesia. Exclusion criteria: History of high blood pressure; history of uncontrolled diabetes; history of cardiovascular disease; history of renal failure; history of cirrhosis; history of smoking or drug abuse; patients with paresthesia level higher than T4.

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization will be done using block randomization method.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

City

Mashhad

Postal code

Approval date

2011-12-08, 1390/09/17

Ethics committee reference number

IR.MUMS.REC.1390.12

Health conditions studied

1

Description of health condition studied

Orthopedic surgery under spinal anesthesia

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

Duration of sensory block

Timepoint

Each 15 minutes after spinal anesthesia

Method of measurement

Pin prick method

Secondary outcomes

1

Description

Blood pressure and heart rate

Timepoint

Before and 5, 10, 15, 30, 60 and 90 minutes after spinal anesthesia

Method of measurement

Monitoring

Intervention groups

1

Description

Control group: they will receive 4 mg of placebo, 90 minutes before spinal anesthesia.

Category

Treatment - Drugs

2

Description

Intervention group: they will receive 4 mg of oral Tizanidine 90 minutes before spinal anesthesia.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Mohammad Alipour

Street address

Ghaem Hospital, Ahmadabad Avenue

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

City

Mashhad

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, Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Mohammad Alipour

Position

Anesthesiologist, Associate Professor

Other areas of specialty/work

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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