

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of Mexiletine effect on duration of sensory and motor block in spinal anesthesia with lidocaine

Protocol summary

Summary

Mexiletine is an oral local anesthetic, (Na channel blocker). Mexiletine is used to relieve postoperative pain and neuropathic pain. It is known as a safe drug in recent trials. In this research the effect of Mexiletine on duration time of sensory and motor block in spinal anesthesia with lidocaine is assessed. In a randomized, double blinded, placebo-controlled clinical trial study, 60 patients who are scheduled for lower limb elective surgery under spinal anesthesia at Shafa and Shahid Bahonar hospitals in 2012 are enrolled. They are randomly assigned in two groups of control and intervention. Intervention group received oral Mexiletine 200 mg 2 hours before operation and control group received placebo. Spinal anesthesia is carried out with lidocaine 5% (100mg) in L2-L3 or L3-L4 space. Both groups are assessed with ECG monitoring, pulse oximetry and blood pressure. The duration time of sensory and motor block is recorded in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201210077488N4**

Registration date: **2012-11-02, 1391/08/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-11-02, 1391/08/12

Registrant information

Name

Mohammadali Haghbin

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 1211 5814

Email address

m.a.haghbin@gmail.com

Recruitment status

Recruitment complete

Funding source

Kerman University of Medical Science

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2012-12-21, 1391/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Mexiletine effect on duration of sensory and motor block in spinal anesthesia with lidocaine

Public title

Effect of Mexiletine on spinal anesthesia with lidocaine

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria; Elective lower limb surgery; Age 18-51 years; Height 150-190cm; Weight 50-90kg; ASA 1,2
Exclusion criteria; Alcohol or narcotic drug consumption; Psychological disorders; Allergic reaction with lidocaine; Infection wound; Open lower limb fracture; Liver disease; Bradycardia; Cardiac block; Seizure; Receive analgesic or opium before operation.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

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**

Kerman University of Medical Sciences(Research and
Tecnology Center)

Street address

Tahmasb Abad Crossed Way ,Kerman

City

Kerman

Postal code**Approval date**

2012-06-28, 1391/04/08

Ethics committee reference number

ka/91/77

Health conditions studied**1****Description of health condition studied**

Anesthesia

ICD-10 code

S80-S89

ICD-10 code description

Injuries to the knee and lower leg

Primary outcomes**1****Description**

Duration time of sensory block

Timepoint

Every 10 min

Method of measurement

The onset time from not sensing pin prick at T10
dermatom until two dermatoms regression from T10

2**Description**

Duration time of motor block

Timepoint

Every 10 min

Method of measurement

The onset time from unabling to elevate knee until
flexion of leg.

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group received oral mexiletine 200 mg 2
hours before operation

Category

Treatment - Drugs

2**Description**

Control group received multivitamin capsul 2 hours
before operation

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

General Operative Room of Shafa Hospital

Full name of responsible person

Dr Haghbin

Street address

Shafa Hospital,Shafa street

City

Kerman

2**Recruitment center****Name of recruitment center**

[Orthopedic Operative Room of Bahonar Hospital

Full name of responsible person

Dr Askarzadeh Mohammad Reza

Street address

Vali Asr Crossed Way,Bahonar Hospital

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Science(Research and Technology center)

Full name of responsible person

Khezry Franak

Street address

Shafa Hospital , Shafa street,Kerman

City

Kerman

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kerman University of Medical Science(Research and Technology center)

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**

Kerman University of Medical science

Full name of responsible person

Dr Sharifzadeh Mahdieh

Position

Resident ofAnesthesiology

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

Bahonar Hospital,Vali Asr crossed way

City

Kerman

Postal code**Phone**

+98 34 1222 8034

Fax**Email**

M H Zamanin 680 @ Yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Kerman University of Medical Science

Full name of responsible person

Dr Haghbin

Position

Assisstan Professor of Anesthesia

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

Shafa Hospital, Shafa Street,Kerman

City

Kerman

Postal code

7618751151

Phone

+98 34121157809

Fax

+98 21 15803

Email

M.A.Haghbin@Gmail.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Kerman University of Medical Science

Full name of responsible person

Dr Haghbin

Position

Assistant Professor of Anesthesia

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

Shafa Hospital,Shafa Street,Kerman

City

Kerman

Postal code

7618751151

Phone

+98 34121157809

Fax

+98 21 15803

Email

M.A.Haghbin@Gmail.com

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