

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 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

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##### Email address

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##### 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

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## Person responsible for scientific inquiries

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**Position**

Assisstan Professor of Anesthesia

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

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## Person responsible for updating data

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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*