Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 effecct of Mexiletine on duration time of sensory and motor block in spinal anesthesie with lidocaine is assesed. In a randomized,double blinded,placebo-controlled clinical trial study, 60 patient who are scheduled for lower limb elective surgery under spinal anesthesia at Shafa and Shahid Bahonar hospitals in 2012 are enrolled. They are randomally assigned in two groups of control and intervation.Intervation group received oral Mexiletine 200 mg 2 hours before operation and control group received placebo.Spinal anesthesia is carried out with lidocaine %5(100mg) inL2-L3 or L3-L4 space .Both groups assessing with ECG monitoring pulse oximetry and blood preasure.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 MedicalSciences
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 18-51years;Height 150-190cm; Weight 50-90kg;ASA 1,2
Exclusion criteria; Alchohole or narcotic drug consumption;Psychological disorders;Allergic reaction with lidocaine;Infection wound ;Open lower limb fracture;Liver disease;Bradycardia;Cardiac block;Seizure;Recieve analgesic or opiuom 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(Resaerch 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
Intervation group received oral mexiletine 200 mg 2 hours before operation
Category
Treatment - Drugs

2

Description
Control group ricieved 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