Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison duration of spinal anesthesia between Lidocain5% and Lidocain5% plus Epinephrine in chronic Opium addiction patients and non addiction patients in lower extremity orthopedic surgery

Protocol summary

Summary

Aim: the aim of the study was to compare of the duration of spinal anesthesia with 5% Lidocaine and 5% Lidocaine coupled with Epinephrine in chronic opium abusers and nonabusers with Lower extremities orthopedic surgery. Design: this clinical trial study was conducted with random allocation and unilateral blinded designed. Method: In this study, the eligible chronic opium abusers and nonabusers randomly allocated into one of two sub groups of methods were available. One sub group was injected with 75 mg of 5% Lidocaine and another sub group was injected with 75 mg of 5% Lidocaine coupled with 0.2 mg Epinephrin in subarachnoid space between the third and fourth lumbar vertebrae. The level of primary sensory was brought to sixth lumbar vertebrae with Changes in the operating room bed slope when the patient was in supine position. Then every ten minutes, the patient's flank was stimulated with a needle for determining the level of sensory. The returning time of 4 levels of sensory to the primary level of sensory were measured and were supposed as Criterion. Participants: Two hundred and one chronic opium abusers and nonabusers with Lower extremities orthopedic surgery were randomly assigned to receive 5% Lidocaine or 5% Lidocaine coupled with Epinephrine for spinal anesthesia in 9 months interval in Kerman. The main outcome variable: assessment of duration of spinal anesthesia with 5% Lidocaine and so the effect of 5% Lidocaine coupled with Epinephrine on the period of spinal anesthesia.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110097745N1**

Registration date: **2011-11-22, 1390/09/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-11-22, 1390/09/01

Registrant information

Name

Afshin Mansourian

Name of organization / entity

YUMS

Country

Iran (Islamic Republic of)

Phone

+98 74 3322 0620

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research University of medical Sciences,Kerman medical University

Expected recruitment start date

2010-07-27, 1389/05/05

Expected recruitment end date

2011-04-22, 1390/02/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison duration of spinal anesthesia between Lidocain5% and Lidocain5% plus Epinephrine in chronic

Opium addiction patients and non addiction patients in lower extremity orthopedic surgery

Public title
Spinal anesthesia with Lidocain
Purpose
Treatment
Inclusion/Exclusion criteria
Exclusion criteria: 1 –patients with higher or lower then sixth lumbar vertebrae's primary sensory level of anesthesia 2- Individuals with BMI (Body Mass Index) more than 30 kg/m2 and less than 20 kg/m2 3- Alcohol abusers 4- Patients who refuse spinal anesthesia 5- patients with Less than one year of opium abusers in addicted group 6- Substance abuse in less than 2 last years for patients in non addicted group 7- Substance abusers other than opium 8- Patients who had developed neuropathy formerly or at present Inclusion criteria: 1- Fifteen to sixty five years old men with 150 to 180 centimeters in height 2- Drug addicted individuals with a history of more than one year abuse; specifically those who had shown withdrawal symptoms with abstention of drugs. 3- Patients who didn't use to any narcotic substances in less than 2 last years ** All information is based on the patient's statements.
Age
From **15 years** old to **65 years** old
Gender
Male

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **210**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kerman University of medical sciences
Street address
BVL Jahad, Neuroscience Research Center of Kerman medical University
City
kerman
Postal code
7619813159
Approval date
2011-05-25, 1390/03/04
Ethics committee reference number
90-7/ع

Health conditions studied

1

Description of health condition studied
Spinal anesthesia
ICD-10 code
y48-3
ICD-10 code description
Local anesthesia

Primary outcomes

1

Description
Duration of spinal anesthesia with Lidocain%5
Timepoint
after 10 minute
Method of measurement
after 10 minute with pinprick on abdomen each 10 minute e %5

Secondary outcomes

1

Description
height
Timepoint
At the time of admit ion
Method of measurement
by patient report

2

Description
age
Timepoint
At the time of admit ion
Method of measurement
by patient report

3

Description
body weight
Timepoint
At the time of admit ion
Method of measurement
by patient report

Intervention groups

1

Description

Addiction patients were selected according to our inclusion and exclusion criteria. All patients were visited the night before surgery and were informed about the study. In these patients were told to use their usual daily dose. All patients were NPO for 8 h before the scheduled surgical procedure. The anesthesiologist who performed the spinal anesthesia and documented the sensory level was blinded to the patient's history of opium abuse. After standard monitoring (electrocardiogram, pulse oxymetry, noninvasive arterial blood pressure, and heart rate), the patients received 500–750 milliliter of lactated solution over 10–15min. Spinal anesthesia were performed with the patient in the sitting position under appropriate aseptic conditions. The L3–4 inter space was funded and with a 24-gauge Sprotte spinal needle was inserted via a midline approach. The needle bevel was oriented cephalic, while 75 milligrams of Lidocaine 5% with dextrose 7.5% was injected in some patients and 75 mg of Lidocaine 5% with dextrose 7.5% plus 0.2 milligrams Epinephrine was injected at a rate of 0.2 milliliter per second in other addicted patients. The patients were placed supine on surgical bed after drug injection. T6 level of sensory was achieved with the help of position maneuvers. Sensory level was assessed with pinprick flank of patient each 10 minute. The level of sensory was then checked and documented till sensory level received to T10. This time that decrease four level of sensory level was recorded and was based of our study

Category

Treatment - Other

2

Description

Non Addiction patients were selected according to our inclusion and exclusion criteria. All patients were visited the night before surgery and were informed about the study. All patients were NPO for 8 h before the scheduled surgical procedure. The anesthesiologist who performed the spinal anesthesia and documented the sensory level was blinded to the patient's history of opium non abuse. After standard monitoring (electrocardiogram, pulse oxymetry, noninvasive arterial blood pressure, and heart rate), the patients received 500–750 milliliter of lactated solution over 10-15min. Spinal anesthesia were performed with the patient in the sitting position under appropriate aseptic conditions. The L3–4 inter space was funded and with a 24-gauge Sprotte spinal needle was inserted via a midline approach. The needle bevel was oriented cephalic, while 75 milligrams of Lidocaine 5% with dextrose 7.5% was injected in some patients, and 75 milligrams of Lidocaine 5%with dextrose 7.5% plus 0.2 milligrams Epinephrine was injected at a rate of 0.2 milliliter per second in other non addicted patients. The patients were placed supine on surgical bed after drug injection. T6 level of sensory was achieved with the help of position maneuvers. Sensory level was assessed with pinprick flank of patient each 10 minute. The level of sensory was then checked and documented till sensory level received to T10. This time that decrease four level of sensory level was recorded and was based of our study

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahonar Hospital

Full name of responsible person

Afshin Mansourian

Street address

Bahonar Hospital, Baghe Meli Square, Kerman

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Kerman University medical Sciences

Full name of responsible person

Doctor Reza Malekpour

Street address

Vice chancellor for research Kerman University medical Sciences ،BLV Jahad, Kerman

City

Kerman

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 Kerman University 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

Kerman University of medical sciences

Full name of responsible person
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Person responsible for scientific inquiries

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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