Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of spinal anaesthesia blockade time with 0.5% bupivacaine-with or without sufentanil-in opium addict patients in comparison with non-addicts: a randomized clinical trial

Protocol summary

Summary

With the prevalence of illicit opioid use in different regions around the world, understanding the effect of opium addiction on the clinical practice is becoming a necessity. 60 patients, who are candidate for lower limb surgery, are selected from patients referred to Dr. Shariati hospital and are randomized into 4 groups. Patients with a history of chronic pain or allergies are excluded from the study. Group 1, no history of opium addiction who receive intrathecal bupivacaine along with 1 mL saline as placebo; group 2, no history of opium addiction who receive intrathecal bupivacaine along with 1 mL sufentanil (5 µg); group 3, Positive history of opium addiction who receive intrathecal bupivacaine along with 1 mL saline as placebo; and group 4, positive history of opium addictions who receive intrathecal bupivacaine along with 1 mL sufentanil (5 µg). Onset time and lenghth of sensory and motor blocks are recorded in the 4 groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012045140N2**
Registration date: **2012-09-11, 1391/06/21**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-09-11, 1391/06/21

Registrant information

Name

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Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2009-04-13, 1388/01/24

Expected recruitment end date

2011-07-19, 1390/04/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of spinal anaesthesia blockade time with 0.5% bupivacaine-with or without sufentanil-in opium addict patients in comparison with non-addicts: a randomized clinical trial

Public title

The effect of opioids on spinal anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: ASA physical status I and II scheduled for orthopedic surgery less than 2 hours. Exclusion criteria: Hepatic or Renal failure; Heart diseases; History of drug allergy; Morbid obesity; History of postoperative nausea and vomiting (PONV); history of motion sickness;

Patients with Chronic pains.

Age
No age limit

Gender
Male

Phase
2

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
Ethic committee, Faculty of medicine of Tehran University of Medical Sciences

Street address
Second floor, Faculty of Medicine, Tehran University of Medical Sciences

City
Tehran

Postal code

Approval date
2010-08-20, 1389/05/29

Ethics committee reference number
381/1388-34

Health conditions studied

1

Description of health condition studied
Regional anesthesia

ICD-10 code
R29.8

ICD-10 code description
unspecified symptoms and signs involving the nervous and musculoskeletal systems

Primary outcomes

1

Description
Block Time

Timepoint
Every 5 minutes

Method of measurement
Pinprick test

Secondary outcomes

1

Description
Post-operative pain

Timepoint
every 4 hours

Method of measurement
Numeric Rating Score(NRS)

Intervention groups

1

Description
group 1, No history of opium addiction who receive intrathecal bupivacaine along with 1 mL saline as placebo.

Category
Placebo

2

Description
group 2, No history of opium addiction who receive intrathecal bupivacaine along with 1 mL sufentanil (5 µg).

Category
Treatment - Drugs

3

Description
group 3, Positive history of opium addictions who receive intrathecal bupivacaine along with 1 mL saline as placebo.

Category
Treatment - Drugs

4

Description
group 4, Positive history of opium addictions who receive intrathecal bupivacaine along with 1 mL sufentanil (5 µg).

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Shariati Hospital
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Shahin Akhoundzade
Street address
Faculty of Medicine, Tehran University of Medical Sciences
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Department of Anesthesiology, Tehran University of Medical Sciences
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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*