Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of epidural anesthesia 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
In this prospective, randomized, double-blind study, we evaluate the onset time and the duration of epidural l anesthesia blockade with or without intrathecal sufentanil in illicit opioid users and non-opium users. In this randomized clinical trial, sixty patients, ASA class I and II scheduled for orthopedic surgery under epidural anesthesia, were allocated into four groups: group 1(No history of opium addiction who received epidural bupivacaine along with 1 mL saline as placebo); group 2(No history of opium addiction whom received epidural bupivacaine along with 1 mL Sufentanil (5 µg));group 3 (Positive history of opium addictions whom receivedepidural bupivacaine along with 1 mL saline as placebo) and group 4(Positive history of opium addictions whom received epidural bupivacaine along with 1 mL Sufentanil (5 µg)).The onset time and duration of sensory and motor blockade was measured.

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT2013070512958N3**
Registration date: **2014-04-02, 1393/01/13**
Registration timing: **retrospective**

Last update:
Update count: **0**
Registration date
2014-04-02, 1393/01/13

Registrant information
Name
Yassaman Aghajani
Name of organization / entity
Tehran university of medical sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 8490 2373
Email address
y-aghajani@razi.tums.ac.ir

Recruitment status
Recruitment complete
Funding source
Tehran University of Medical Sciences

Expected recruitment start date
2013-03-19, 1391/12/29
Expected recruitment end date
2013-03-19, 1391/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of epidural anesthesia 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
Duration of epidural anesthesia in opium addict patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: 1.American Society of Anesthesiologist physical status (ASA) class I and II 2.lower limb orthopedic surgery under spinal anesthesia (lasting less than 3 hours) 3.any contraindications to epidural anesthesia 4.confirming the written consent 5. patients with addiction to any substance other than opium 6.

male patients 7. patients aged between 20-50 years old Exclusion criteria: 1.patients with history of cardiac disease 2.patients with history of respiratory disease 3.patients with history of psychological disease 4. patients with history of allergic reaction to local anesthetics 5. orthopedic surgeries lasts more than 3 hours

Age
From **20 years** old to **50 years** old

Gender
Male

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
Ethics Committee, Faculty of Medicine

Street address
Faculty of Medicine, Tehran University of Medical Sciences and Health Care

City
Tehran

Postal code

Approval date
2012-05-26, 1391/03/06

Ethics committee reference number
130/176/91/د

Health conditions studied

1

Description of health condition studied
pain

ICD-10 code
R52.0

ICD-10 code description
acute pain

Primary outcomes

1

Description
onset of sensory block

Timepoint
immediately after injection of the drug till surgical insicion

Method of measurement
chronometer

2

Description
duration of sensory block

Timepoint
incision till end of yhe surgery and start of postoperative pain

Method of measurement
chronometer

Secondary outcomes

1

Description
duration of motor block

Timepoint
disable to move till enabling to move postoperative

Method of measurement
chronometer

2

Description
onset of motor block

Timepoint
disable to move from surgical incision

Method of measurement
chronometer

3

Description
surgery duration

Timepoint
during the operation

Method of measurement
chronometer

4

Description
Intraoperative Fluid

Timepoint
during surgery

Method of measurement
Crystaloid Fluid registration chart

Intervention groups

1

Description
intervention group: On arrival in the operating room, standard monitoring was established (electrocardiography, noninvasive blood pressure, pulse oximetry and heart rate) and lactated ringer solution 7 ml. kg-1 was administered. Then, with the patient in the sitting position and using an aseptic technique, a 16-gauge Touhy needle was inserted via a midline approach into the L3–4 or L4–5 interspaces. Patients in group 1 received 80 mg of 0.5% hyperbaric bupivacaine along with 20 microgram sufentani
Category
Treatment - Drugs

2

Description
control group: On arrival in the operating room, standard monitoring was established (electrocardiography, noninvasive blood pressure, pulse oximetry and heart rate) and lactated ringer solution 7 ml. kg-1 was administered. Then, with the patient in the sitting position and using an aseptic technique, a 16-gauge Touhy needle was inserted via a midline approach into the L3–4 or L4–5 interspaces. Patients in group 1 received 80 mg of 0.5% hyperbaric bupivacaine along with 1ml normal saline 0.9%
Category
Treatment - Drugs

3

Description
intervention group: On arrival in the operating room, standard monitoring was established (electrocardiography, noninvasive blood pressure, pulse oximetry and heart rate) and lactated ringer solution 7 ml. kg-1 was administered. Then, with the patient in the sitting position and using an aseptic technique, a 16-gauge Touhy needle was inserted via a midline approach into the L3–4 or L4–5 interspaces. Patients in group 1 received 80 mg of 0.5% hyperbaric bupivacaine along with 20 microgram sufentani in opium addict patients
Category
Treatment - Drugs

4

Description
intervention group: On arrival in the operating room, standard monitoring was established (electrocardiography, noninvasive blood pressure, pulse oximetry and heart rate) and lactated ringer solution 7 ml. kg-1 was administered. Then, with the patient in the sitting position and using an aseptic technique, a 16-gauge Touhy needle was inserted via a midline approach into the L3–4 or L4–5 interspaces. Patients in group 1 received 80 mg of 0.5% hyperbaric bupivacaine along with1ml normal saline 0.9% in opium addict patients
Category
Treatment - Drugs

Recruitment centers

1

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

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Shahin Akhound zade
Street address
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
Faculty of Medicine, Tehran University of Medical Sciences and Health Care
Full name of responsible person
Yasaman Aghajani
Position
resident of anesthesiology
Other areas of specialty/work
Street address
Shariati Hosp, North Karegar Ave
City

Tehran
Postal code
1411713135
Phone
+98 21 8490 2373
Fax
Email
y-aghajani@razi.tums.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ali Movafegh
Position
professor
Other areas of specialty/work
Street address
Shariati Hosp, North Karegar Ave
City
Tehran
Postal code
1411713135
Phone
+98 21 8490 2373
Fax
Email
movafegh@sina.tums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
FAculty of Medicine, Tehran university of medical sciences
Full name of responsible person
Yasaman Aghajani
Position
Resident of Anesthesiology
Other areas of specialty/work
Street address
City
Postal code
Phone
+98 21 8490 2372
Fax
Email
y-aghajani@razi.tums.ir
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