Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effects of adding Fentanyl to Bupivacaine in spinal anesthesia in opium addicted patients

Protocol summary

Summary

The aim of this study is determining the effects of adding Fentanyl to Bupivacaine in spinal anesthesia in opium addicted patients. This study is a randomized double blind clinical trial on 60 male opium addicted patients who are admitted for lower abdomen and extremity surgeries. Inclusion criteria are; patients' consent for spinal anesthesia, lower abdomen and extremity surgery , patient who consumes opium orally or by inhalation and shows withdrawal symptoms if do not consume it. Exclusion criteria are using other sort of narcotics by the patient and history of pulmonary or cardiac diseases. The patients are divided into two groups of 30 ones, randomly. In this study we use simple sampling method and selecting the simple sample is executed by draw. Patients in first group undergo spinal anesthesia with 12.5 mg Bupivacaine plus 0.5 ml sterile instilled water and in another group spinal anesthesia is performed using 12.5 mg bupivacaine and 25µg fentanyl. In operative room 750 ml Ringers is given to them firstly and their vital signs are measured and documented. Midazolam 1mg is given to patient for relaxation and the level of senselessness is determined by skin test using a needle. The patients who do not reach to desired level (T10) are dismissed from the study. The time of asking analgesic by the patient is considered as the time of beginning the pain. During the surgery the patients' vital signs are recorded every 5 minutes and in recovery room every 15 minutes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012092210900N1**
Registration date: **2013-09-22, 1392/06/31**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2013-09-22, 1392/06/31

Registrant information

Name

Hosein Sattari

Name of organization / entity

kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 1322 2250

Email address

sattari@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Kerman University of Medical Sciences

Expected recruitment start date

2012-08-01, 1391/05/11

Expected recruitment end date

2013-03-01, 1391/12/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of adding Fentanyl to Bupivacaine in spinal anesthesia in opium addicted patients

Public title

Comparison of two method of spinal anesthesia in opium addicts

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1) patient's consent of spinal anesthesia. 2) The patient who are admitted for lower abdomen and lower extremity surgery. 3) patients who are in the age range of 65-15 year 4) Patients in the height range between 185 - 150 cm 5)opium addict is a person who have used opium orally or inhales it at least for one year 6) surgery length of 80 to 150 minutes 7) No history of other drug abuse and psychological disorders. 8) Weight between 50 to 85 kg. exclusion criteria: 1- consuming other kinds of drugs 2- history of pulmonary or cardiac diseases 3-history of disorders which have absolute or partial contraindication for spinal anesthesia 4- history of hypersensitivity to fentanyl or bupivacaine.

Age

From **15 years** old to **65 years** old

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

Not used

Assignment

Other

Other design features

After approving by Ethic Committee of Kerman University of Medical Sciences, informed consent will be obtained from the patients. The method of sampling is simple randomization which amongst studied members of community who are referred to operation rooms of Afzalipoor, Shafa and Bahonar hospitals of kerman, one sample will be selected from the listed groups in the chances box by the patient accidentally. The medication is prepared by study leader and the anesthesiologist and technician who are responsible for taking care of the patient are blind to the medication as well as the patient. The preparation of patients in both group are similar and all the patients must be NPO for 8 hours before operation. The patients are notified of consuming regular opium as their usual pattern.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical sciences

Street address

Jomhoori boulevard

City

Kerman

Postal code

Approval date

2012-05-19, 1391/02/30

Ethics committee reference number

k/91/41

Health conditions studied

1

Description of health condition studied

Opium Addiction

ICD-10 code

F11

ICD-10 code description

Mental and behavioural disorders due to use of opioids

Primary outcomes

1

Description

the onset of pain after surgery

Timepoint

after operation

Method of measurement

asking the patient

Secondary outcomes

1

Description

blood pressure

Timepoint

every 5 minutes and every 15 minutes in PACU

Method of measurement

digital monitoring device

2

Description

the length of sensory nerves block

Timepoint

at 40,50,60,70,80,90,100,110 and 120 minutes

Method of measurement

skin stimulation test

3

Description

the length of motor nerves block

Timepoint

at 40,50,60,70,80,90,100,110 and 120 minutes

Method of measurement

asking the patient to move his legs

4

Description
the time of onset the analgesia
Timepoint
after performing the procedure
Method of measurement
skin stimulation test

5

Description
nausea and vomiting
Timepoint
throughout the operation and in PACU
Method of measurement
asking the patient

6

Description
Itching
Timepoint
throughout the operation and in PACU
Method of measurement
asking the patient

7

Description
Shivering
Timepoint
throughout the operation and in PACU
Method of measurement
observation

Intervention groups

1

Description
Patients in control group undergo spinal anesthesia with 12.5 mg Bupivacaine (20mg/4ml, manufactured by ICI Pharmaceuticals India Limited) plus 0.5 ml sterile instilled water
Category
Treatment - Drugs

2

Description
In intervention group spinal anesthesia is performed using 12.5 mg bupivacaine (20mg/4ml, made by ICI Pharmaceuticals India Limited) and 25µg fentanyl (0.5mg/10ml, manufactured by Aburaihan Co.Iran).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Afzalipoor hospital
Full name of responsible person
Azam Karimi
Street address
Afzalipoor Hospital
City
Kerman

2

Recruitment center
Name of recruitment center
Shafa Hospital
Full name of responsible person
Azam Karimi
Street address
St. shafa, Shafa Hospital
City
Kerman

3

Recruitment center
Name of recruitment center
Bahonar Hospital
Full name of responsible person
Azam Karimi
Street address
Bahonar Hospital
City
Kerman

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of Research Kerman University of Medical Sciences
Full name of responsible person
Fatemeh Hassani
Street address
Tahmasbabad Square, Ebnesina Street
City
Kerman
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Deputy of Research Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Azam Karimi

Position

Resident of anesthesia

Other areas of specialty/work

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Position

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Other areas of specialty/work

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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