

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 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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Afzalipoor Hospital

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## Person responsible for updating data

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Hoseyn Sattari

**Position**

Anesthesiologist

**Other areas of specialty/work**

**Street address**

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**City**

Kerman

**Postal code**

## 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*