

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Comparison of hemodynamic changes and patients satisfaction(analgesia) in patients undergoing prostate biopsy surgery with two methods of anesthesia Sedation and Saddle

#### Protocol summary

##### Summary

This study is a single blind, randomized clinical trial. The purpose of this study is comparison of hemodynamic changes and patients satisfaction (analgesia) in patients undergoing prostate biopsy surgery with two methods of anesthesia Sedation and Saddle. Inclusion criteria: the patient's complete satisfaction; ASA class I & II and age between 20-50 years old. Exclusion criteria: contraindications of Saddle Anesthesia (patient refusal; infection at the site of planned needle puncture; elevated intracranial pressure); allergy or contraindication to any of the drugs used in the study; severe cardiovascular, respiratory, metabolic, or neurologic diseases. 120 Patients will be allocated into two groups according to table of random numbers. Group "one" 5-10 minutes before biopsy will receive one dose 1 mcg /kg Intravenous Fentanyl and one dose 0.05 mg/kg Intravenous Midazolam for sedation. In group "two" Saddle anesthesia with one dose 12 mg of hyperbaric bupivacaine will perform for patients in the sitting position at L3-L4 interspace using a 25-gauge Whitacre needle. After drug injection, the patients must be stay in the sitting position at least 3-5 minutes and then the patients will turn to supine position. Hemodynamic changes and patients' satisfaction with VAS (Visual Analogue Scale) at end of biopsy, 10, and 20 minutes after surgery will measured.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013102315136N1**  
Registration date: **2013-11-08, 1392/08/17**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2013-11-08, 1392/08/17

##### Registrant information

###### Name

mohamad sahraeian

###### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 1222 0168

###### Email address

sahraeian.m@ajums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Ahvaz University of Medical Sciences

##### Expected recruitment start date

2014-02-04, 1392/11/15

##### Expected recruitment end date

2014-06-05, 1393/03/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of hemodynamic changes and patients satisfaction(analgesia) in patients undergoing prostate biopsy surgery with two methods of anesthesia Sedation and Saddle

##### Public title

Comparison of hemodynamic changes and patients satisfaction (analgesia) in patients undergoing prostate biopsy surgery with two methods of anesthesia Sedation and Saddle

#### **Purpose**

Prevention

#### **Inclusion/Exclusion criteria**

Inclusion criteria: the patient's complete satisfaction; - ASA class I & II and age between 20-50 years old .

Exclusion criteria: contraindications of Saddle Anesthesia( patient refusal; infection at the site of planned needle puncture; elevated intracranial pressure); allergy or contraindication to any of the drugs used in the study; severe cardiovascular, respiratory, metabolic, or neurologic diseases.

#### **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: **120**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Single blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

##### **Street address**

No. 21, Ave. 1, Golestan Blvd.

##### **City**

Ahvaz

##### **Postal code**

6135733777

#### **Approval date**

2012-10-12, 1391/07/21

#### **Ethics committee reference number**

Eth-636

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Pain during Prostate biopsy

#### **ICD-10 code**

R10.2

#### **ICD-10 code description**

Pelvic and perineal pain

## **Primary outcomes**

### **1**

#### **Description**

Hemodynamic Changes

#### **Timepoint**

End of Biopsy, 10, and 20 minutes after surgery

#### **Method of measurement**

Blood Pressure Measurement

## **Secondary outcomes**

### **1**

#### **Description**

Patient Satisfaction of Pain Control

#### **Timepoint**

End of Biopsy, 10, and 20 minutes after surgery

#### **Method of measurement**

Visual Analogue Scale

## **Intervention groups**

### **1**

#### **Description**

Group "one" 5-10 minutes before biopsy will receive one dose 1 mcg /kg Intravenous Fentanyl and one dose 0.05 mg/kg Intravenous Midazolam for Sedation.

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Group "two" Saddle anesthesia with one dose 12 mg of hyperbaric bupivacaine will perform for patients in the sitting position at L3-L4 interspace using a 25-gauge Whitacre needle.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Imam Khomeini Educational Hospital

**Full name of responsible person**

Dr Amir Salari

**Street address**

No. 307, Kokab Street, Masters Alley, Golestan Blvd.

**City**

Ahvaz

fatahi.m@ajums.ac.ir mostafafatahi777@gmail.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Mohsen Sahraeian

**Position**

Resident of Anesthesia

**Other areas of specialty/work****Street address**

No. 12, Enghelab Chamber, Golestan

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**Web page address****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research, Ahvaz Jundishapur

University of Medical Sciences

**Full name of responsible person**

Dr. Mostafa Fegghi

**Street address**

No. 21, Ave. 1, Golestan Blvd.

**City**

Ahvaz

**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, Ahvaz Jundishapur

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**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

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**Position**

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**Email****Person responsible for updating data****Contact****Name of organization / entity**

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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*