Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 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

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Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences
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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 Analoge 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

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 Feghhi
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

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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