Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

To evaluate the effect of intracapsular bupivacaine injection in post open prostatectomy pain control

Protocol summary

Summary

Objectives: To evaluate the effect of intracapsular bupivacaine injection in post open prostatectomy pain control Design: Randomized, Double blind, Placebo controlled, single center Setting and conduct: 38 patients aged from 55 to 100 years old with good general condition who referred for obstructive urinary symptoms due to benign prostatic hyperplasia and having the indication for open prostatectomy, after being aware of the study and filling the informed consent will enter the study. Inclusion criteria: Patients who are candidate for open prostatectomy due to obstructive urinary symptom and do not have allergy to bupivacaine Exclusion criteria: Prostatic capsule perforation during the surgery Intervention: Open prostatectomy will be performed in both groups. In the intervention group after removing the prostatic adenoma, 20 ml of 0.5% bupivacaine will be injected in the posterior prostatic capsule from 4 to 8 o clock. In the control group 20 ml of normal saline will be injected in the before mentioned area. Main outcome measures: Amount of analgesic used and visual analog scale of pain

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015061822168N2**
Registration date: **2015-12-21, 1394/09/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-12-21, 1394/09/30

Registrant information

Name

Dinyar Khazaeli

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Jundishapur University of Medical Sciences

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2015-09-23, 1394/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To evaluate the effect of intracapsular bupivacaine injection in post open prostatectomy pain control

Public title

Decreasing pain in prostate surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients who are candidate for open prostatectomy due to obstructive urinary symptom and do not have allergy to bupivacaine Exclusion criteria: Prostatic capsule perforation during the surgery

Age

From **55 years** old to **100 years** old

Gender
Male

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **38**
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
Ethical Committee of Ahvaz Jundishapur University of Medical Sciences
Street address
ground floor, Ahvaz Jundishapur University of Medical Sciences, Golestan BLvd.
City
Ahvaz
Postal code
61357-15794
Approval date
2015-05-30, 1394/03/09
Ethics committee reference number
IR.AJUMS.REC.1394.39

Health conditions studied

1

Description of health condition studied
Benign prostatic hyperplasia
ICD-10 code
N40
ICD-10 code description
Hyperplasia of prostate

Primary outcomes

1

Description
The amount of pethidine used
Timepoint
Every our in the first 8 hours from the surgery and then every 3 hours therafter up to 24 hours
Method of measurement
The amount of used drug in miligram

2

Description
Amount of pain
Timepoint
Every our in the first 8 hours from the surgery and then every 3 hours therafter up to 24 hours
Method of measurement
Based on pain visual analog scale which is filled by the patient from 0 to 10

Secondary outcomes

1

Description
Side effects
Timepoint
24 hours after the surgery
Method of measurement
Any changes in blood pressure and cardiac arrhythmias

Intervention groups

1

Description
In the intervention group after removing the prostatic adenoma, 20 ml of 0.5% bupivacaine will be injected in the posterior prostatic capsule from 4 to 8 o clock.
Category
Prevention

2

Description
In the control group after removing the prostatic adenoma, 20 ml of normal saline will be injected in the posterior prostatic capsule from 4 to 8 o clock.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Dr. Dinyar Khazaeli
Street address
Azadegan Avenue
City
Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Jundishapur University of Medical Sciences

Full name of responsible person
Nader Saki

Street address
Office of Vice-chancellor of research and technology, ground floor, Jundishapur University of Medical Sciences, 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, 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
Dr. Dinyar Khazaeli

Position
Fellowship of uro-oncology, Assistant Professor of Urology, Research Vice-Chancellor of Imam Khomein

Other areas of specialty/work

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Person responsible for updating data

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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