

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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)

Phone

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Email address

khazaeli-d@ajums.ac.ir

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 thereafter 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 thereafter 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 Khomeini

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