Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Comparitive Study Between the effect of Intra techal Petidine and Lidocaine versus Standard Lidocaine on Hemodynamics in Open Prostatic Surgery

Protocol summary

Summary

The aim of this double blind clinical trial is to compare the effect of standard lidocaine versus a mixture of standard lidocaine and pethidine on hemodynamics of patients who are candidates for open prostatectomy. All patients will be catheterized with gauge 18 needles and will receive 500 cc of normal saline before the procedure. Patient will be randomly allocated into two groups of intervention and control. Sample sizes in the two groups are the same and 39 patient. Monitoring in the two groups are the same and routine (pulse oximetery, NIBPmonitoring, core temperature monitoring, ECG monitoring, input and out put, need for sympatomimetic, and need for pain control drugs). The amount of blood loss will be estimated by anesthesiologist and the surgeon in two groups through consensus. In control group all patient will receive lidocaine 5% up to 2 millilitre and in case group all patient will receive lidocaine %5 and 0.5 mg/kg pethidine up to 2 millilitre .Drug will be injected intratechally in all patient by a size 24 needle via space L4-L5. After injection of drug all patients will be put in horizontal position and the anesthesia level in all participants will be T8.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903061936N2**
Registration date: **2010-10-15, 1389/07/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-10-15, 1389/07/23

Registrant information

Name
Abdolreza Najafi Anaraki
Name of organization / entity
Bushehr University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Bushehr university of medical science

Expected recruitment start date

2009-12-08, 1388/09/17

Expected recruitment end date

2010-11-07, 1389/08/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparitive Study Between the effect of Intra techal Petidine and Lidocaine versus Standard Lidocaine on Hemodynamics in Open Prostatic Surgery

Public title

Comparitive Study Between the effect of Intra techal Petidine and Lidocaine versus Standard Lidocaine on Hemodynamics in Open Prostatic Surgery

Purpose

Prevention

Inclusion/Exclusion criteria

All patient who are candidates for open prostatectomy are eligible to participate in the study. Exclusion criteria: age above 75 and below 45, history of sensitivity to opioid, unwilling to participate and coagulopathy

Age

From **45 years** old to **75 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

other

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee ofBushehr university of medical science

Street address

Bushehr university of medical science

City

Bushehr

Postal code

Approval date

2009-04-10, 1388/01/21

Ethics committee reference number

4314/3/18/20/دپ

Health conditions studied

1

Description of health condition studied

To study effect of intratechal standard lidocaine and mixture of lidocaine and pethidine on hemodynamic of patient in open prostatectomy

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

Hemodynamic change (BP change)

Timepoint

pre induction and in minute 1,2,3,5,10,15,20,25,30,45,60,90,120

Method of measurement

NIBP monitoring

Secondary outcomes

1

Description

Temperature change

Timepoint

60 minute

Method of measurement

Temperature Monitoring

2

Description

Post operative nausea and vomiting

Timepoint

120 minute

Method of measurement

observation

3

Description

Post operative pain

Timepoint

120 minute

Method of measurement

Analogous pain score

4

Description

Intra operative blood loss

Timepoint

120 minute

Method of measurement

observation

Intervention groups

1

Description

In control group all patient received lidocaine 5% intratechally (2 cc)and needle entrance is space L4-L5.Other intervention in two group is same.

Category

Prevention

2

Description
In case group all patient received lidocaine 5% pulse pethidine 0/5 mg/kg up to 2 cc intratechally and needle entrance is space L4-L5.Other intervention in two group is same.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Fateme Zahra hospital

Full name of responsible person
Najafi Anaraki

Street address
Bushehr, Fateme Zahra hospital

City
Bushehr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research committee of medical science of bushehr university

Full name of responsible person
Dr Asadi

Street address
Bushehr, Faculty of Medicine

City
Bushehr

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Research committee of medical science of bushehr university

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

Person responsible for scientific inquiries

Contact

Name of organization / entity
Bushehr university of medical science

Full name of responsible person
Dr Najafi Anaraki

Position
Assistant professor

Other areas of specialty/work

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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