Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Intravenous Hyoscine on Catheter Induced Bladder Discomfort after Transurethral Resection of Prostate

Protocol summary

Summary

Objective: To determine the effect of intravenous injection of hyoscine on the discomfort caused by the urinary tract catheter after trans-urethral resection of the prostate. Study Design: A randomized, double-blind.Inclusion criteria: patients underwent trans-urethral resection of the prostate. Exclusion criteria: decision to open prostatectomy surgery instead of TURB, uncontrolled underlying diseases, chronic pelvic pain, opium addiction, contra indications of the intravenous of hyoscine, spinal anesthesia. Interventions: 50 patients divided into two groups of intervention and control group. Patients in the intervention group received intravenous injection of 20 mg hyoscine N-butyl bromide slow over a minute at the end of the surgery. Patients in the control group received one ml of saline as placebo. Furthermore, the amount of intraoperative bladder irrigation, size and type of the folly catheter was recorded in the data collection forms. . Patients in the both groups were checked every half hour for 2 hours in the recovery room from arrival to the recovery room. The intensity of catheter-related urinary tract discomfort, dry mouth - tachycardia (heart rate over a hundred), nausea, vomiting, blurred vision, severe discomfort were checked. All patients with the grade 2 and 3 of catheter discomfort received a slow intravenous injection of 25 mg pethedine.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013071013934N1**
Registration date: **2015-03-04, 1393/12/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-03-04, 1393/12/13

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Shiraz University of Medical Sciences

Expected recruitment start date

2013-08-24, 1392/06/02

Expected recruitment end date

2014-02-21, 1392/12/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Intravenous Hyoscine on Catheter Induced Bladder Discomfort after Transurethral Resection of Prostate

Public title

Effect of Hyoscine on Reducing Catheter Related Discomfort

Purpose

Prevention

Inclusion/Exclusion criteria
Inclusion criteria: patients underwent trans-urethral resection of the prostate. Exclusion criteria: decision to open prostatectomy surgery instead of TURB; uncontrolled underlying diseases; chronic pelvic pain; opium addiction; contra indications of the intravenous of hyoscine; spinal anesthesia.
Age
No age limit
Gender
Male

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **80**
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
Ethic Committee of Shiraz University Of Medical Sciences
Street address
Central Building of Shiraz University of Medical Sciences, Zand Street
City
Shiraz
Postal code
Approval date
2013-08-04, 1392/05/13
Ethics committee reference number
CT-P-92-4904

Health conditions studied

1

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

Primary outcomes

1

Description
Severity of catheter related bladder discomfort
Timepoint
Just arriving to recovery room then every 30 minutes until 2 hours
Method of measurement
According to 4 grads of CRBD described in this study

Secondary outcomes

1

Description
Dry mouth
Timepoint
During two hours being in the recovery room
Method of measurement
By asking from patients

2

Description
Tachycardia(HR>100)
Timepoint
During two hours being in the recovery room
Method of measurement
Tachycardia is measured through continues monitoring

3

Description
Nausea and Vomiting
Timepoint
During two hours being in the recovery room
Method of measurement
By asking from patients

4

Description
Blurred vision
Timepoint
During two hours being in the recovery room
Method of measurement
By asking from patients

Intervention groups

1

Description
20mg slow intravenous injection of Hyoscine N-butyl Bromide , single dose at the end of the operation.
Category
Treatment - Drugs

2

Description
One milliliters normal saline (placebo) slowly intravenous injection, single dose, end of the operation
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Namaze Hospital
Full name of responsible person
Dr Pourya Adibi
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Anesthesiology Office, Namazi Hospital, Zand Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Shiraz University of Medical Sciences
Full name of responsible person
Dr Seed Basir Hashemi
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Vice Chancellor for Research, Shiraz University of Medical Sciences, 7th floor, Central Building of Shiraz University of Medical Sciences, Zand Street
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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, Shiraz 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