

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison the efficacy of prescription Anticholinergic alone and with Diazepam in treatment of pain related to bladder spasm in post operation of open prostatectomy

Protocol summary

Study aim

Comparison the efficacy of prescription Anticholinergic alone and combination with Diazepam in treatment of pain related to bladder spasm in post operation of open prostatectomy

Design

Two arm parallel group ,non randomised , a blinded with control group clinical trial.

Settings and conduct

According to sever pain arising from ladder Spasm after open prostatectomy , in order to better method for decrease pain and based on done studies , designed a study that include 2 groups of 20 patients with Bladder Spasm after open prostatectomy in Shohadaye Khalij Fars Hospital of Bushehr . to one group given Tolterodine ta 2mg every 12 hours and second group recived Tolterodine tab 2mg every 12 hours and Diazepam tab 5mg every night ; then patients of 2 groups assessed and compared based on received Methadone amp 5mg and pain severity before , 6hrs , 12hrs , 18 hrs , 24hrs , 36hrs and 48hrs after the giving the drugs .

Participants/Inclusion and exclusion criteria

all patients with bladder spasm after open prostatectomy enter to study and patients that use anti depressent and narcotic drugs and opiums , patients that have oerate under generalize anesthesia , patients with sever ischemic diseases and patient that have contraandication for Tolterodine and Diazepam , exit from study.

Intervention groups

first group received Tolterodine tab every 12 hrs and second group received Tolterodine tab every 12 hrs and Diazepam tab 5mg every nighte and , both groups received Methadon ampul 5mg if pain score (according NRS) be upper than 4 .

Main outcome variables

effect of diazepam on bladder spasm pain , effect of

Tolterodine on Bladder Spasm pain , Access to effective analgesic cpmbination therapy , more effective decreased of patients's pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190127042515N1**

Registration date: **2019-02-11, 1397/11/22**

Registration timing: **prospective**

Last update: **2019-02-11, 1397/11/22**

Update count: **0**

Registration date

2019-02-11, 1397/11/22

Registrant information

Name

fatemeh dehghani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 77 3332 2081

Email address

fa.dehghani.94@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the efficacy of prescription Anticholinergic alone and with Diazepam in treatment of pain related to bladder spasm in post operation of open prostatectomy

Public title

Effect of Diazepam in treatment of bladder spasm

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All of patient with bladder spasm after open prostatectomy

Exclusion criteria:

Opium and anti depressent and narcotic drug user
General anesthesia
Oversensitivity to Tolterodine and Diazepam
Unstable hemodynamic state
Severe ischemic heart diseases

Age

No age limit

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

Only urologist prescribe the drugs and valuator , patient and analisor don` t know about prescribed drug . only one valuator relation with patients directly

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Bushehr University of Medical Science

Street address

Sabzabad Ave , Salman Farsi Ave, Bushehr University of Medical Science

City

Bushehr

Province

Boushehr

Postal code

7518759577

Approval date

2018-10-09, 1397/07/17

Ethics committee reference number

IR.BPUMS.REC.1397.057

Health conditions studied**1****Description of health condition studied**

bladder spasm

ICD-10 code

N32.89

ICD-10 code description

Other specified disorders of bladder

Primary outcomes**1****Description**

Pain scor according to Numerical Rating Scale

Timepoint

Befor intervention , 6 , 12 , 18 , 24 , 36 and 48 hours after intervention

Method of measurement

Nimerical Ratig Pain Scale

2**Description**

Recieved methadone amounts

Timepoint

During 48 hours after prescriptin of drugs

Method of measurement

Methadon ampuls amount

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: Tolterodine tab 2mg N =1 every 12 hrs for 48hrs

Category

Treatment - Drugs

2

Description

Intervention group: Tolterodine tab 2mg N =1 every 12 hrs for 48hrs and Diazepam tab 5mg N=1 nightly

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Khalij Fars Hospital

Full name of responsible person

Mohammad Zaki Abbasi

Street address

Ayatollah Taleghani St, Shohadaye Khalij Fars Hospital

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7517933755

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MPGH@BPUMS.AC.IR

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Dr. Afshin Ostovar

Street address

Sabzabad Ave , Salman Farsi Ave, Bushehr University of Medical Science

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Pkarshenasan@Yahoo.com

Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Boushehr University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Mohammad Zaki Abbasi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

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Latest degree

Specialist

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Person responsible for updating data

Contact

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Fatemeh Dehghani

Position

Medical Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

اطلاعات بیشتری وجود ندارد

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All of data are publishable

When the data will become available and for how long

One year after publish the results

To whom data/document is available

All of person

Under which criteria data/document could be used

Request of access to data and documents are acceptable if the purpose is education and treatment.

From where data/document is obtainable

Requests are given to Bushehr University of Medical Science Vice President of Research and Email of Fatemeh Dehghani or Mohammad Zaki Abbasi.

What processes are involved for a request to access data/document

raised the question will be answered at less than 5 days

Comments