

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Efficacy of Gabapentin for Prevention of Postoperative Catheter-related Bladder Discomfort in Patients Undergoing open prostatectomy

Protocol summary

Summary

The aim of our study is, to evaluated gabapentin for preventing CRBD and pain severity in patient undergoing open prostatectomy. 42 patients undergoing open prostatectomy will be randomly allocated to 2 intervention and placebo groups. First group will receive stat dose of 300 mg and 100 mg q8 hour of gabapentin and the other one will receives placebo. The patients will be observed for the incidence and severity of CRBD in the postoperative period and pain severity (VAS index) .Morphine amount that patient may need, will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014063017811N4**
Registration date: **2014-07-06, 1393/04/15**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-07-06, 1393/04/15

Registrant information

Name

Shayan Amjadi

Name of organization / entity

Students Research Committee, Arak University of Medical Science

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Recruitment status

Recruitment complete

Funding source

This study was supported by a grant from Office of Vice-Chancellor for Research

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2014-08-23, 1393/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Gabapentin for Prevention of Postoperative Catheter-related Bladder Discomfort in Patients Undergoing open prostatectomy

Public title

Gabapentin and CRBD

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: Patients of American Society of Anesthesiologists (ASA) physical status I-II undergoing elective open prostatectomy surgery under spinal anesthesia ; requiring catheterization of the urinary bladder ; 50–80 kg of weight exclusion criteria: Patients with history of OAB (urinary frequency >3 times at night and > 8 times in 24 hours) ; neurogenic bladder; diabetes mellitus ; Parkinson's disease and impaired renal function ; chronic use of opiates or sedatives ; antacid uptake in the past 48 hours ; hypersensitivity to amide local anesthetics or gabapentin

Age

No age limit

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 42

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

Arak University of medical science

Street address

Arak University of Medical Science, Sardasht, Arak,
Iran

City

Arak

Postal code

Approval date

2013-07-24, 1392/05/02

Ethics committee reference number

92-157-13

Health conditions studied

1

Description of health condition studied

Postoperative Catheter-related Bladder Discomfort in
Patients Undergoing open prostatectomy

ICD-10 code

T83.0

ICD-10 code description

Mechanical complication of urinary (indwelling) catheter

Primary outcomes

1

Description

Catheter-related bladder discomfort(CRBD) severity

Timepoint

at hours 2,5,24,48,72 after surgery

Method of measurement

based on asking patients based on Likert scale

2

Description

pain severity

Timepoint

at hours 2,5,24,48,72 after surgery

Method of measurement

based on VAS index

Secondary outcomes

1

Description

Total morphine requirement

Timepoint

at hours 2,6,24,48,72

Method of measurement

counting amount of morphine that will be injected to
patient

2

Description

postoperative sedation

Timepoint

at hours 2,6,24,48,72

Method of measurement

clinical examination

3

Description

postoperative N/V

Timepoint

at hours 2,6,24,48,72

Method of measurement

clinical examination and history taking

Intervention groups

1

Description

patients in gabapentin group will received the study drug
orally with sips of water 2 hours before the
administration of spinal anesthesia then they will receive
gabapentin capsules 100 mg per 8 hours as a
maintenance therapy till 72 hours

Category

Treatment - Drugs

2

Description

matching placebo capsules contain starch will be given
to placebo group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital , Amirkabir hospital

Full name of responsible person

Dr.Ali Cyrus

Street address

valiasr hospital , valiasr square , Arak , Iran

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Science,Office of Vice
Chancellor for Research

Full name of responsible person

Davoud Hekmatpo

Street address

Arak univercity of medical science , Arak , Iran

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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

Arak University of Medical Science,Office of Vice
Chancellor for Research

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

Medicine faculty , Aarak University of Medical Science

Full name of responsible person

Javad Aghamohammadi

Position

Medical student

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Full name of responsible person

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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