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 Universiry of Medical Science
Country
Iran (Islamic Republic of)
Phone
+98 86 3417 3502
Email address
sh.amjadi@arakmu.ac.ir

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 ; antiacid 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
City
Arak
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
Other areas of specialty/work
Street address
Arak University of Medical Science , Sardasht , Arak , Iran
City
Arak
Postal code
Phone
+98 86 3417 3502
Fax
Email
javad.aghamohammadi@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Department of Urology, Medicine Faculty,Arak University Of Medical Science
Full name of responsible person
Ali Cyrus
Position
Urology specialist, Associate professor
Other areas of specialty/work
Street address
Arak University Of Medical Science, Arak , Iran
City
Arark
Postal code
Phone
+98 86 3417 3502
Fax
Email
Cyrus.a@arakmu.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Medicine faculty , Aarak University of Medical Science
Full name of responsible person
Javad Aghamohammadi
Position
Medical student
Other areas of specialty/work
Street address
Arak University of Medical Science , Sardasht , Arak , Iran
City
Arak
Postal code
Phone
+98 86 3417 3502
Fax
Email
javad.aghamohammadi@yahoo.com
Web page address

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