Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of oral pregabalin and local anesthesia simultaneous administration effect on pain of patients undergoing prostate biopsy refered to imam hospital of Urmia

Protocol summary

Study aim
Evaluation of oral pregabalin and local anesthesia simultaneous administration effect on pain of patients undergoing prostate biopsy referred to imam hospital of Urmia

Design
After stratification and randomization, all of patients basic information, will be collect and divided to 2 groups: first, undergone TRUS biopsy of prostate under local anesthesia with Lidocaine second, those have given 100 mg Pregabalin Cap 6 hours before the procedure despite of their BMI and then go on TRUS biopsy of prostate . All of patients will get Lat Decubitus or Lithotomy position for their biopsy . Trans rectal US probe will be prepare for biopsy localizing and then go under TRUS biopsy of prostate with biopsy needle . 18 G needle attaached to US probe will be use. And then pain after biopsy , 1 an 6 hour ,will be questioned by a nurse in recovery room in operation ward due to pain analog questionnaire.

Settings and conduct
Referred patients to Urmia Imam Khomeini Hospital

Participants/Inclusion and exclusion criteria
Inclusion criterion: male patients with PSA ≥4.0 ng/mL. Exclusion criteria: lithotomy position for prostate biopsy is impossible for participants; prior pelvic pain before prostate biopsy; TURP history; hormonal therapy or radiotherapy history; existing any ano-rectal pathology

Intervention groups
Control group use local anesthesia with Lidocaine gel and intervention group will receive single oral dose of 100mg Pregabaline an hour before of biopsy,

Main outcome variables
Pain after prostate biopsy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200205046388N1**
Registration date: **2020-11-16, 1399/08/26**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-16, 1399/08/26**
Update count: **0**

Registration date
2020-11-16, 1399/08/26

Registrant information

Name
Hossein Aghamohamadpour

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 44 3198 8749

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-10, 1399/08/20

Expected recruitment end date
2020-12-10, 1399/09/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of oral pregabalin and local anesthesia

simultaneous administration effect on pain of patients undergoing prostate biopsy refered to imam hospital of Urmia

Public title
Evaluation of oral pregabalin administration on pain of patients undergoing prostate biopsy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Male patients with PSA ≥4.0 ng/mL Lithotomy position for prostate biopsy is possible for participants
Exclusion criteria:
Prior pelvic pain before prostate biopsy TURP history Hormonal therapy or radiotherapy history Existing any Ano-rectal pathology
Age
From **20 years** old
Gender
Male

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **52**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is based on blocks stratification and triple blind clinical trial, any patients will received any placebo or pregabalin cap. randomly. after determination of patients number (52 patients), according to epidemiological methods ,they stratified to A or B randomly and will receive placibo or pregabalin cap. according seal up pockets specified A or B.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Because of placebo and drugs similarity, not only the participants but also the primary nurse prescribe the drugs, will not informed of basic trial and then the nurse who will collect data will not be known kind of prescribed capsule.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Urmia University of Medical Sciences
Street address
Vice chancellor for resaerch, Central building of UMSU. Resalat Avn.
City
Urmia
Province
West Azarbaijan
Postal code
3175874867
Approval date
2020-01-29, 1398/11/09
Ethics committee reference number
IR.UMSU.REC.1398.466

Health conditions studied

1

Description of health condition studied
Prostate cancer
ICD-10 code
C61
ICD-10 code description
Malignant neoplasm of prostate

Primary outcomes

1

Description
Pain after prostate biopsy
Timepoint
1 and 6 hours after biopsy
Method of measurement
Pain Analogue Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: single dose of PREGABALIN SOBHAN DAROU (Iran), 100MG CAP will prescribe in patients which be under routine TRUS biopsy prostate with Lidocaine local anesthesia, one hour before than biopsy.
Category
Treatment - Drugs

2

Description
Control group: patients underwent prostate biopsy with

routine Lidocaine local anesthesia and receive placebo with no further intervention and with similar procedure of prostate biopsy

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam khomeini hospital of Urmia

Full name of responsible person

Aghamohamadpour Hossein

Street address

Imam khomeini Hosp., Ershad blvd., Homafar 2 ave.

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aghamohamadpour.h@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Fatemeh Hajmohamadian

Street address

Central Campus of Urmia University of Medical Sciences, Resalat blvd., Jahad Ave.

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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

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Tayyebi Azar Ali

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Urology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Clinical and demographic findings after personal data deletion.

When the data will become available and for how long
one year after publish

To whom data/document is available
urologist in research or clinical fields

Under which criteria data/document could be used
for repeating of research or experimental use of data

From where data/document is obtainable
urology ward- Imam hospital in Urmia

What processes are involved for a request to access data/document
Direct request from researcher by web based connection

Comments