

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of oral pregabalin and local anesthesia simultaneous administration effect on pain of patients undergoing prostate biopsy referred 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 attached 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 Pregabalin 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)

Phone

+98 44 3198 8749

Email address

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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 referred 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 \geq 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 placebo 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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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., Jihad 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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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