

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

The study of selective cyclooxygenase-2 inhibitor and non-selective cyclooxygenase inhibitor effect in patients with benign prostatic hyperplasia who are on alpha-blocker drugs and its association with PV, PVR, PSA, LUTS

Protocol summary

Summary

In this study, we want to investigate and compare the effects of two drugs of Celecoxib and Naproxen on lower urinary tract symptoms, prostate specific antigen, prostate volume, and post void residual urinary volume in patients with moderate to severe prostate hyperplasia. These variables are evaluated at the beginning of the study and 3 months after the intervention. For evaluation of the effect of Celecoxib and Naproxen, three groups of 20 people are examined. To 20 patients, 200 mg of Celecoxib daily plus 400 micrograms of Tamsulosin daily is given, and 20 others receive 500 mg of Naproxen daily plus 400 g of Tamsulosin every day, and 20 others as the control group, receive only 400 mg of Tamsulosin daily. Each group of 3 groups is given daily 20 mg Omeprazole for prevention of gastrointestinal disorders and for the homogenization of groups. In this study, men over the age of 50 who have a moderate to severe benign prostatic hyperplasia with an international prostate symptom score of more than 8 and conditions in accordance with the specifications of research Can be enrolled.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2017091836241N2**

Registration date: **2017-11-02, 1396/08/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-11-02, 1396/08/11

Registrant information

Name

Zahra Madadi

Name of organization / entity

Tehran university medical science

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2017-06-20, 1396/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study of selective cyclooxygenase-2 inhibitor and non-selective cyclooxygenase inhibitor effect in patients with benign prostatic hyperplasia who are on alpha-blocker drugs and its association with PV, PVR, PSA, LUTS

Public title

Evaluation of the selective cyclooxygenase-2 inhibitor and non-selective cyclooxygenase inhibitor in benign

prostatic hyperplasia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Men over the age of 50 who have moderate to severe benign prostatic hyperplasia with international prostate symptoms score greater than 8; benign prostate diagnosis; no Liver problem; no active infections; no history of frequent urinary tract infections; no clear malignancy; no stone in the urethra, ureter and bladder; no history of urolithiasis; no prostate transurethral removal; no history of inflammation of the prostate; absence of a microscopy hematuria and advanced; no history of or retention; no history of trauma of the lower back and perineal and urethra; no history of cystoscopy; no history of sexually transmitted infections; no history of pelvic or urological surgery; non diabetic; non-neurological diseases (CNA, Parkinson's disease, MS and lumbar disks); history of congestive heart failure; no history of pelvic radiotherapy; no history of tuberculosis; no renal failure with creatinine higher than 1.3; no history of antidepressants, antihistamines, bronchodilators, diuretics and narcotics in the last 3 months; no history of psychological diseases (such as Schizophrenia, severe depression); lack of experience in the use of effective drugs in the treatment of benign prostatic hypertrophy in the last 3 months, including 5α-alpha-reductates and alpha-blockers, and phosphodiesterase inhibitors; no history of persistent alcohol and caffeine intake; high fluid intake; gastrointestinal ulcer or gastrointestinal bleeding.
Exclusion criteria: Patient disagreement; unwillingness to follow up the study program for any reason; sensitivity to the drug and its ingredients: the use of the drug causes patient dissatisfaction; the acute urinary problems so that the person has urinary retention and the condition is so severe that it requires catheterization and surgery; prostate cancer

Age
From **50 years** old

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University,
Pharmaceutical Sciences Branch

Street address

Yakhchal Street, Gholhak, Shariati

City

Tehran

Postal code

19395-6466

Approval date

2016-11-14, 1395/08/24

Ethics committee reference number

IR.IUA.PS.REC.1395.35

Health conditions studied

1

Description of health condition studied

Benign prostate hyperplasia

ICD-10 code

N40

ICD-10 code description

Hyperplasia of prostate

Primary outcomes

1

Description

International Prostate Symptom Score

Timepoint

Before intervention and 3 months after start of intervention

Method of measurement

questionnaire

2

Description

quality of life

Timepoint

Before intervention and 3 months after start of intervention

Method of measurement

questionnaire

Secondary outcomes

1

Description

Prostate Specific Antigen

Timepoint

Before intervention and 3 months after start of intervention

Method of measurement

Blood test

2**Description**

Prostate Volume

Timepoint

Before intervention and 3 months after start of intervention

Method of measurement

Abdominal ultrasound

3**Description**

Post-Void Residual Urine Volume

Timepoint

Before intervention and 3 months after start of intervention

Method of measurement

Abdominal ultrasound

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

Intervention group 1: Capsule Tamsulosin 0.4 mg half an hour after meals once a day plus capsule Celecoxib 200 mg with food once a day plus capsule Omeprazole 20 mg half an hour before breakfast

Category

Treatment - Drugs

2**Description**

Intervention group 2: Capsule Tamsulosin 0.4 mg half an hour after meals once a day plus Tablet Naproxen 500 mg with food once a day plus capsule Omeprazole 20 mg half an hour before breakfast

Category

Treatment - Drugs

3**Description**

Control group: Capsule Tamsulosin 0.4 mg half an hour after meals once a day

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center**

Name of recruitment center

Bo-ali Hospital Tehran

Full name of responsible person

Zahra Madady

Street address

Damavand Avenue, Imam Hossein Square,

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Deputy of Research of Azad University of Pharmaceutical Sciences

Full name of responsible person

Seyyed Jalaluddin Hosseini Ghonche

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Yakhchal Street, Gholhak, Shariati

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Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Deputy of Research of Azad University of Pharmaceutical Sciences

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**

Hospital BO-Ali Tehran, Urology Clinic

Full name of responsible person

Reza Valipour

Position

PhD in Urology

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of Clinical Pharmacy, Islamic Azad University, Pharmaceutical Sciences Branch

Full name of responsible person

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Position

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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