Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 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

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Name of organization / entity
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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 Schizopherenia, 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
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Damavand Avenue, Imam Hossein Square,
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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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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
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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