Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

Evaluation of the effects of silymarin and calciferol on LUTS in patients with benign prostatic hyperplasia with normal and lower than normal serum vitamin D levels

Protocol summary

Study aim
. Evaluation of the effects of silymarin and calciferol on IL-6, PSA, IPSS in patients with benign prostatic hyperplasia with normal serum vitamin D levels 2. Evaluation of the effects of silymarin and calciferol on IL-6, PSA, IPSS in patients with benign prostatic hyperplasia with lower than normal serum vitamin D levels

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 60 yards. The table of even and odd numbers was used for randomization

Settings and conduct
The location is in the clinic of Bu Ali Hospital and after the patient's visit, the distribution of patients in groups is done by a third person.

Participants/Inclusion and exclusion criteria
Men 50 years and older with prostate size referred to the clinic of Bu Ali Hospital

Intervention groups
Silymarin is given in patients with benign prostatic hyperplasia who are taking tamsulosin concomitantly.

Main outcome variables
The rate of improvement of the patient's quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200906048641N1**
Registration date: **2020-10-09, 1399/07/18**
Registration timing: **retrospective**

Last update: **2020-10-09, 1399/07/18**
Update count: **0**

Registration date
2020-10-09, 1399/07/18

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-21, 1398/09/30

Expected recruitment end date
2020-08-21, 1399/05/31

Actual recruitment start date
2019-12-21, 1398/09/30

Actual recruitment end date
2020-08-30, 1399/06/09

Trial completion date
2020-08-30, 1399/06/09

Scientific title
Evaluation of the effects of silymarin and calciferol on LUTS in patients with benign prostatic hyperplasia with normal and lower than normal serum vitamin D levels

Public title
Evaluation of the effects of silymarin and calciferol on LUTS in patients with benign prostatic hyperplasia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
PSA<4 50-80 years old - mild to moderate benign prostatic hyperplasia IPSS > 8
Exclusion criteria:
- kidney failure - Urine retention - Prostate cancer - Liver disease - Active infection - Malignancy - Stone in urethra ,bladder , ureters - Prostate inflammation - Hematuria - History of cystoscopy - History of pelvic or urology surgery - Diabetes - Neurological diseases(Parkinson , MS , CVA ,waist disk) - Heart failure - History of pelvic radiotherapy - History or concomitant use of antidepressant ,antihistamine , bronchodilator ,diuretic , narcotic - History of 5alpha reductase inhibitor and phosphodiesterase inhibitors drugs use - History of tuberculosis - History of urinary tract and perineum trauma - History of permanent consumption of alcohol , caffeine and excessive fluid intake - History of psychological diseases (schizophrenia , severe depression) History of waist - History or concomitant use of yohimbine , metronidazole , anticholinergic drugs

Age
From **50 years** old

Gender
Male

Phase
2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **60**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Referral patients who have inclusion criteria and no exclusion criteria are included in the study.After determining the patient's vitamin D level, patients are divided into two groups of normal and lower than normal vitamin D levels. Patients are randomly assigned to one of the two groups by simple random allocation method and the intervention belongs to the same group (normal group: treatment: tamsulosin tablets at a dose of 0.4 mg daily and silymarin capsules 240 mg and control group tamsulosin tablets with 0.4 mg daily and placebo capsules every 12 hours) and lower than normal group (treatment: tamsulosin tablets at a dose of 0.4 mg daily and silymarin capsules at a dose of 240 mg every 12 hours and perl calciciferol 50,000 U and the control group at a dose of tamsulosin tablets at a dose of 0.4 mg daily and placebo capsule for 12 hours receive a number and perl calciciferol (50,000 U).The randomization unit will be the patients. In each envelope, one of the four codes (A = normal therapy and code (B = normal control C) below normal therapy D) will be placed lower than normal control. Envelopes will be provided to the researcher. With each patient, one of the envelopes will be randomly selected by the researcher and introduced as a study group. The layering approach is not used. There will be no concealment in the study.

Blinding (investigator's opinion)
Double blinded

Blinding description
The study is a double-blind clinical trial. The results of the study were blinded at the patient level and outcome assessments. The drug and placebo capsules were filled in the same packages with the same labeling . Only the researcher could decrypt the contents of each drug package based on the defined code.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Faculty of Pharmacy, Azad University

Street address
Dr. Shariati St. - Gholhak - First Glacier St.

City
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Province
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Postal code
1111111223

Approval date
2019-12-11, 1398/09/20

Ethics committee reference number
IR.IAU.TMU.REC.1398.170

Health conditions studied

1

Description of health condition studied
Benign Prostatic Hyperplasia

ICD-10 code
N40.0

ICD-10 code description
Enlarged prostate without lower urinary tract symptoms

Primary outcomes

1

Description
Improve quality of life{Description of outcome variable: prostate volume (measurement intervals at the beginning of the study / three months later)

Timepoint
1 month and 3 month

Method of measurement

How to measure the variable: ultrasound}

2

Description
Changes in the severity of symptoms
Timepoint
Begin, 1 m, 3m
Method of measurement
IPSS

3

Description
PSA change
Timepoint
Begin, 3m
Method of measurement
serology

Secondary outcomes

empty

Intervention groups

1

Description
Patients with serum vitamin D levels receive tamsulosin tablets (Farabi Company) at a dose of 0.4 mg daily and silymarin capsules 240 mg (manufactured by Rose Pharmed Biotechnology Company) every 12 hours for 3 months.
Category
Treatment - Drugs

2

Description
Control group: Patients with serum levels of vitamin D normal, receive tamsulosin tablets(Farabi company) at a dose of 0.4 mg daily and placebo capsules every 12 hours for 3 months
Category
Treatment - Drugs

3

Description
Intervention group: Patients with lower than normal serum levels of vitamin D, tamsulosin tablets (drug) at a dose of 0.4 mg daily and silymarin capsules 240 mg (manufactured by Rose Pharmed Farabi Company) every 12 hours and a cholecalciferol 50000 U therapeutic dose Based on serum levels, they receive vitamin D for 3 months
Category
Treatment - Drugs

4

Description
Control group: Patients with serum vitamin D levels below normal, tamsulosin tablets (drug) at a dose of 0.4 mg daily and a placebo capsule every 12 hours and perl calciciferol 50,000 U received a therapeutic dose based on serum vitamin D levels for 3 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Booali hospital
Full name of responsible person
Dr.Mehdi Rajabi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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http://iaups.iautmu.ac.ir/fa
Grant name
not
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

No

Title of funding source

-

Proportion provided by this source

10

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr.Mehdi Rajabi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The paper will be publish

When the data will become available and for how long

1400

To whom data/document is available

researchers

Under which criteria data/document could be used

email

From where data/document is obtainable

college

What processes are involved for a request to access data/document

email to corresponging

Comments