Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

The effect of vitamin D supplements on benign hypertrophy

Protocol summary

Study aim
The effect of vitamin D supplements on Benign prostatic hypertrophy
Design
Clinical trials with control group, with parallel groups, blind, randomized
Settings and conduct
At Ziaiean Hospital, men who are over 50 are eligible to enter the study. First, vitamin D supplementation (50,000 units) is given every two weeks and the placebo is given to control group for 6 months. After the completion of the course, sonography is performed for intervention and control patients . After the completion of the course, the plan is again performed for patients with ultrasound intervention and control.
Participants/Inclusion and exclusion criteria
Man over 50 years old ,Asymptomatic or mild symptoms Benign prostatic hypertrophy based on the IPSS questionnaire, Patients with benign prostatic hypertrophy Exit criteria :History of kidney stones, bladder and urinary tract stones, Having prostate or bladder cancer or prostate surgery, Use of GnRH agonists, anti-androgens and any hormonal drug in the past six months.
Intervention groups
The intervention group received vitamin D and the control group received placebo randomly.
Main outcome variables
Prostate Volume

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180922041089N3**
Registration date: **2019-09-03, 1398/06/12**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-05, 1399/06/15**
Update count: **1**
Registration date
2019-09-03, 1398/06/12

Registrant information
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Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-11-22, 1397/09/01
Expected recruitment end date
2019-11-22, 1398/09/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of vitamin D supplements on benign hypertrophy

Public title
The effect of vitamin D on the treatment of prostate hypertrophy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Man over 50 years old Asymptomatic or mild symptoms of benign prostatic hypertrophy based on the IPSS

questionnaire. Patients with benign prostatic hypertrophy

Exclusion criteria:

BMI greater than 35 or pathologic weight loss (weight loss over 10% of body weight in the last 6 months) History of kidney stones, bladder and urinary tract Having prostate or bladder cancer or prostate surgery Acute or chronic prostatitis or frequent urinary tract infections• History of acute urinary retention or repeated catheters in the last three months Use of GnRH agonists, anti-androgens and any hormonal drug in the past six months, the use of herbal and non-herbal medicines to control and treat BPH The history of chronic diseases such as CVA, HTN, COPD, liver and kidney disease, and cancers .. Taking medications that affect vitamin D metabolism such as corticosteroids, phenytoin, phenobarbital, or regular use of vitamin D supplements over the past 3 months Taking diuretics such as Lasix and ... Alcohol consumption

Age

From **50 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be divided into two groups using Permuted Block Randomization. To create a random sequence in a block randomization approach, use the website https://www.sealedenvelope.com. Also, to allocation concealment, the random sequence is assigned to a particular person. The researcher then communicates with the person according to the order of entry of the participants to the study and questions the random allocation of the participant to the specific group. For each drug (each drug box), a random number is created, defined by a number (code) and placed on the envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

En In order to eliminate the bias caused by the patient's or doctor's knowledge of the received treatment type and its possible effect on the outcome of the study, the study is double blinded. Considering that the vitamin D and placebo tablets are placed in the same capsule, the patient and the assessing physician are not aware of the type of received drug.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Ethics Committee for Biomedical Research

Street address

Abuzar St, Ziaian Hospital, Tehran Town

City

Tehran

Province

Tehran

Postal code

1366736511

Approval date

2018-07-21, 1397/04/30

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1397.257

Health conditions studied

1

Description of health condition studied

Benign prostatic hypertrophy

ICD-10 code

N40

ICD-10 code description

Benign Prostatic Hypertrophy

Primary outcomes

1

Description

Prostate Volume

Timepoint

At the beginning of the study and six months later

Method of measurement

sonography

Secondary outcomes

1

Description

Severity of clinical symptoms

Timepoint

At the beginning of the study, 3 months later, 6 months later

Method of measurement

IPSS questionnaire

2

Description

PSA

Timepoint
At the beginning of the study, 3 months later, 6 months later
Method of measurement
laboratory kit

3

Description
Vitamin D
Timepoint
At the beginning of the study, 3 months later, 6 months later
Method of measurement
blood test

Intervention groups

1

Description
Intervention group: The intervention group includes people 50 years old and older who receive pills Vitamin D with a dose of 50000 for 6 months.This drug should be taken every two weeks.
Category
Treatment - Drugs

2

Description
The control group includes people 50 years of age and older who will receive the placebo vitamin D for 6 months. This drug should be taken every two weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ziaeian Hospital
Full name of responsible person
Mansour ShaporSamaee
Street address
Abuzar St, Ziaian Hospital, Tehran Town
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Grant Student Thesis
Proportion provided by this source
10
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
Tehran University of Medical Sciences
Full name of responsible person
Abolfazl Zendedel
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
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Person responsible for updating data

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Family Physician

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

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

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

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

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