

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 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

Name

Abolfazl Zendehtel

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5517 6031

Email address

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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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s.masamaei@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammadali Sahraeeian

Street address

Keshavarz Blvd - Qods St, Tehran University of Medical Sciences

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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 scientific 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

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shapour Mansoursamaei

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

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