Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Effect of vitamin D on biochemical indicators and clinical symptoms in military personnel with benign prostatic hyperplasia

Protocol summary

Study aim
Determining the effect of vitamin D intake on changes in biochemical levels related to prostate size in patients with benign prostatic hyperplasia.

Design
Clinical trial with control group, factorial, double-blind, randomized, phase 4 on 60 patients. Randomization using Excel software.

Settings and conduct
People referring to the urologist of Samen Al-Aimeh Hospital in Mashhad. The researcher is blind and the colleague will assist the patients in designing the study.

Participants/Inclusion and exclusion criteria
suffered from BPH based on the diagnosis of a clinical specialist Signing a informed consent form No entry: History of prostate cancer

Intervention groups
The group receiving vitamin D soft gel 5000 units once a week for 8 weeks.

Main outcome variables
Serum levels of vitamin D. Serum levels of calcium and phosphorus Serum levels of Testosterone and LH Serum PSA levels Prostate size

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180201038585N9**
Registration date: **2020-11-02, 1399/08/12**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-02, 1399/08/12**
Update count: **0**

Registration date
2020-11-02, 1399/08/12

Registrant information

Name
Karim Parastouei

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8248 3516

Email address
parastouei@bmsu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-10-22, 1399/08/01

Expected recruitment end date
2021-03-10, 1399/12/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of vitamin D on biochemical indicators and clinical symptoms in military personnel with benign prostatic hyperplasia

Public title
Effect of vitamin D on prostate

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Suffered from BPH based on the diagnosis of a clinical specialist Signing of a informed consent form

Exclusion criteria:
Allergy to vitamin D

Age

No age limit

Gender

Male

Phase

4

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was performed by block randomization method. Random sequence generation was done using table of random numbers by a third trained person. Allocation concealment was performed using sealed envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

Vitamin d and its placebos will manufactured by Abureyhan company. All Vitamin d and its placebo will provided by Abureyhan company in prepacked boxes numbered for each patient according to the randomization sequence. Vitamin d and its placebos will in the same form of package and the patients and researcher will not aware of the content of the pack until the end of trial

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Baqiyatallah University of Medical Sciences

Street address

Tehran, Vanak Square, Mulla Sadra St., South Sheikh Baha'i St.

City

Tehran

Province

Tehran

Postal code

1435916471

Approval date

2020-08-19, 1399/05/29

Ethics committee reference number

IR.BMSU.REC.1399.300

Health conditions studied

1

Description of health condition studied

benign prostatic hyperplasia

ICD-10 code

N40

ICD-10 code description

Enlarged prostate

Primary outcomes

1

Description

Serum levels of prostate-specific antigen (PSA)

Timepoint

At the beginning of the study and 56 days after weekly intake of vitamin D.

Method of measurement

Using a specific kit

Secondary outcomes

1

Description

serum levels of vitamin d

Timepoint

At the beginning of the study and 56 days after the intervention

Method of measurement

with using specific kit

2

Description

serum levels of calcium and phosphorus

Timepoint

At the beginning of the study and 56 days after the intervention

Method of measurement

with using specific kit

3

Description

Serum levels of testosterone and LH

Timepoint

At the beginning of the study and 56 days after the intervention

Method of measurement

with using specific kit

4

Description

size of prostate

Timepoint

At the beginning of the study and 56 days after the intervention

Method of measurement

with using sonogrphy

5

Description

Clinical signs of prostate hyperplasia

Timepoint

At the beginning of the study and 56 days after the intervention

Method of measurement

Using a validated questionnaire

Intervention groups

1

Description

Intervention group:There are 30 people in this group who are studied once a week for 8 weeks using a vitamin D supplement containing 50,000 international units of D3. Drugs and placebo are purchased from Abureihan Pharmaceutical Company.

Category

Prevention

2

Description

Control group: The "control group" uses the same placebo as the vitamin D supplement. In the control group, one placebo will be taken weekly for 8 weeks.Drugs and placebo are purchased from Abureihan Pharmaceutical Company.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Samen Al-Aimeh Hospital, Mashhad

Full name of responsible person

Reza Azarian moghaddam

Street address

57 Imam Khomeini Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah 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?

Yes

Title of funding source

Bagheiat-allah University of Medical Sciences

Proportion provided by this source

100

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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Karim Parastouei

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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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
All data can be shared after identifying individuals.
When the data will become available and for how long
Access period starts 6 months after the results are published.
To whom data/document is available
It will be available only to researchers working in academic and scientific institutions
Under which criteria data/document could be used
Statistical analysis is allowed on the documents and can be used after the data is published.
From where data/document is obtainable
Email the project executor. parastouei@bmsu.ac.ir
What processes are involved for a request to access data/document
After receiving the email, the documents will be sent to the person within a maximum of one week.
Comments