Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The effect of vitamin D supplementation on clinical symptoms and serum levels of some inflammatory factors in men with chronic nonbacterial prostatitis

Protocol summary

Study aim
Determining the effect of vitamin D supplementation on clinical symptoms and serum levels of some inflammatory factors in men with chronic non-bacterial prostatitis

Design
Double-blind randomized clinical trial with control group, with parallel groups, phase 3 on 48 patients, block randomization method and allocation concealment method

Settings and conduct
A double-blind randomized controlled clinical trial, Sample includes people referring to the urology clinic of Imam Khomeini Hospital in Ahvaz with chronic pelvic pain syndrome. Patients, the clinical caregiver, and the evaluator of treatment outcomes are kept unaware of the type of treatment assigned to patients

Participants/Inclusion and exclusion criteria
Inclusion criteria : Men in their 20s and 50s with symptoms of chronic non-bacterial prostatitis (CPPS) Criteria for non-entry: Alcohol consumption, following special diets, regular use of antioxidant supplements over the past 6 months and other diseases, history of surgery in the last 3 years, urethral stricture, fever and chills

Intervention groups
Intervention group: 24 people receiving vitamin D 1000 international units (25 micrograms) per day for 8 weeks Control group: 24 people receiving 25 micrograms of starch daily (placebo) for 8 weeks

Main outcome variables
Clinical signs, PSA, IL1 β

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210717051914N1**
Registration date: **2021-08-23, 1400/06/01**
Registration timing: **prospective**

Last update: **2021-08-23, 1400/06/01**
Update count: **0**

Registration date
2021-08-23, 1400/06/01

Registrant information

Name
Hengameh Abrishamkar

Name of organization / entity

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Iran (Islamic Republic of)

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+98 61 3321 9296

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-23, 1400/07/01

Expected recruitment end date
2023-03-21, 1402/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of vitamin D supplementation on clinical symptoms and serum levels of some inflammatory

factors in men with chronic nonbacterial prostatitis

Public title
effect of vitamin D on the treatment of prostatitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Men 50-20 years old Symptoms of CPPS include perineal and lower back pain, obstructive symptoms and urinary retention, NGU (non-gonorrheal urethritis)
Exclusion criteria:
alcohol consumption Follow certain diets Regular use of antioxidant or anti-inflammatory supplements for the past 6 months Other diseases (diseases affecting blood calcium levels such as hyperparathyroidism , metabolic diseases such as diabetes .....) Inflammatory diseases History of surgery in the last 3 years Urinary tract stenosis fever and chills
Age
From **20 years** old to **50 years** old
Gender
Male

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling will be done by simple non-probability method, so that from the beginning of the study, all patients who meet the inclusion criteria will be selected as a sample and this will continue until the final sample size. allocation of patients to each of the study groups will be accomplished with the block random method and using sextet blocks
Blinding (investigator's opinion)
Double blinded
Blinding description
To reduce the possibility of information bias, the double-blind method is used; In this way, both the patients and the researcher and the person evaluating the results of the treatment will be kept unaware of the type of treatment assigned to the people. Also, in order to reduce the possibility of selection bias, after randomization, the Allocation Concealment method or the use of unit codes is used. In this way, all containers containing supplements and placebos, which are quite similar in appearance, are coded as A and B by someone outside the study, and the code can be broken only by the person who did the numbering.
Placebo
Used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Golestan Blvd
City
Ahvaz
Province
Khouzestan
Postal code
1579461357
Approval date
2021-07-31, 1400/05/09
Ethics committee reference number
IR.AJUMS.REC.1400.289

Health conditions studied

1

Description of health condition studied
Prostatitis
ICD-10 code
N41.1
ICD-10 code description
Chronic prostatitis

Primary outcomes

1

Description
Prostate Specific Antigen
Timepoint
At the beginning and 8 weeks after the intervention
Method of measurement
Based on laboratory measurements (ng / ml) by ELISA method

2

Description
Interleukin-1 beta
Timepoint
At the beginning and 8 weeks after the intervention
Method of measurement
Based on laboratory measurements (ng / ml) by ELISA method

3

Description
Clinical signs
Timepoint
At the beginning and 8 weeks after the intervention
Method of measurement
Using two questionnaires: International Score of Prostate Symptoms (IPSS) and the National Institute of Chronic Prostate Symptoms Index (NIH-CPSI)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 24 people, receiving vitamin D 1000 international units (25 micrograms) of health aid manufacturer, one per day for 8 weeks
Category
Treatment - Drugs

2

Description
Control group: 24 people receiving placebo tablets containing 25 micrograms of starch, made by Ahwaz Jundishapur University School of Pharmacy, one per day for 8 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Urology Clinic of Imam Khomeini Hospital, Ahvaz
Full name of responsible person
Hengameh Abrishamkar
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr Mehdi Ahmadi Moghadam
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Web page address
https://www.ajums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Hengameh Abrishamkar
Position
Master student
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Nutrition
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Person responsible for updating data

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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