Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of vitamin D supplementation on blood pressure in hypertensive patients with vitamin D deficiency

Protocol summary

Summary

Objective: To assess the effect of vitamin D supplementation on blood pressure in hypertensive patients with vitamin D deficiency (2)Design: Parallel randomized controlled double blind trial (3)Setting and conduct: After obtaining inform consent, the patients were randomized into two groups receiving vitamin D3 or placebo pearl using table of random numbers, blood pressure was measured and compared before and after the intervention between two groups (4)Participants including major eligibility criteria:42 hypertensive patients with vitamin D deficiency(serum 25-hydroxy vitamin D lower than 30 nmol/lit) referring to Azadshahr Health and treatment center in yazd (Iran) (5)Intervention: Receiving 50000 IU vitamin D3 supplementation (group1) or placebo(group2) for 8 weeks(one pearl per week) (6)Main outcome measures: Hypertension

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012090310724N1**
Registration date: **2012-09-25, 1391/07/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-09-25, 1391/07/04

Registrant information

Name
Saba Loloei
Name of organization / entity
Shahid Sadoogi University Of Medical Sciences and Health Services
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Sadoogi University of Medical Sciences and Health Services

Expected recruitment start date

2012-09-23, 1391/07/02

Expected recruitment end date

2013-09-21, 1392/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D supplementation on blood pressure in hypertensive patients with vitamin D deficiency

Public title

The effect of vitamin D supplementation on blood pressure in hypertensive patients with vitamin D deficiency

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with Systolic Blood Pressure equal or more than 140 mmHg ; and Diastolic Blood Pressure equal or more than 90 mmHg. ; and serum 25-hydroxy vitamin D3 lower than 30 ng/ml ; living in Yazd province; aged 25-50 years; not to be alcohol user or smoker or addicted ; without any liver or Coronary-artery

or renal or Gastro Intestinal disorders; not using oral or injection of corticosteroids; not using cardiac glycosides or antiepileptic drugs; not using multi vitamins or supplements containing vitamin D, Calcium, Magnesium, Phosphorus or their analogs in past 3 mounts; not using injection of vitamin D in past 6 mounts; Exclusion criteria: any change in dosage or type of anti hypertension drugs; not following the study protocol. Exclusion criteria: any change in dosage or type of anti hypertension drugs; not following the study protocol.

Age
From **25 years** old to **50 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Moral Committee of Shahid Sadoogi University of Medical Sciences and Health Services

Street address
Bahonar sq

City
Yazd

Postal code

Approval date
2012-07-28, 1391/05/07

Ethics committee reference number
61670/1/17/پ

Health conditions studied

1

Description of health condition studied
hypertension

ICD-10 code
I10

ICD-10 code description
Essential (primary) hypertension

Primary outcomes

1

Description
hypertension

Timepoint
before and 8 week after intervention

Method of measurement
mercurial sphygmomanometer

Secondary outcomes

1

Description
serum Calcium

Timepoint
before and 8 weeks after intervention

Method of measurement
laboratory biochemical measurements

2

Description
serum 25- Hydroxy vitamin D

Timepoint
before and 8 weeks after intervention

Method of measurement
laboratory biochemical measurements _nmol/lit

3

Description
serum PTH

Timepoint
before and 8 weeks after intervention

Method of measurement
laboratory biochemical measurements

4

Description
serum phosphorus

Timepoint
before and 8 weeks after intervention

Method of measurement
laboratory biochemical measurements

Intervention groups

1

Description
50000IU vitamin D3 pearl(oral supplements),for 8 weeks, one pearl per week

Category
Treatment - Drugs

2

Description
placebo pearl, for 8 weeks, one pearl per week
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
AZAD SHAHR health and treatment center of YAZD
Full name of responsible person
Dr Mohammadreza Mirjalili
Street address
Safaeie St.
City
Yazd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Shahid Sadoogi University of Medical Sciences
Full name of responsible person
Dr Hassan Mozaffari Khosravi
Street address
Bahonar sq
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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
Vice chancellor for research, Shahid Sadoogi University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty