Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

Effect of vitamin D supplementation versus placebo on hypertension in patients with vitamin D deficiency: a double blind randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of vitamin D supplementation versus placebo on hypertension in patients with vitamin D deficiency. Design: a double blind randomized clinical trial. Setting and conduct: The eligible patients with vitamin D deficiency who will refer to Farshchian Hospital during the study period will be enrolled into the trial. Inclusion criteria: Age of 18 to 75 years; systolic blood pressure equal to or greater than 140 mmHg or diastolic blood pressure equal to or greater than 90 mmHg in tow times; vitamin D deficiency. Exclusion criteria: Pregnancy; secondary hypertension; renal failure; a history of using vitamin D or calcium during the last three months; using Thiazide-type diuretics. Intervention group: Routine anti-hypertensive drugs plus gelatin tablet vitamin D (Calciferol) based on Vitamin D serum level (50,000 U once a week oral in subjects with Vitamin D serum level less than 20 ngr/mL and 1000 U in subjects with serum level between 20 to 30 ngr/mL) for 2 months Control group: Routine anti-hypertensive drugs plus gelatin tablet placebo once a week for 2 months. Primary outcome: Measuring systolic and diastolic blood pressure in sitting position from the right hand using mercury sphygmomanometer before intervention and then monthly for 2 months. Secondary outcome: Measuring serum Calciferol before intervention and then monthly for 2 months through laboratory test. Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Therefore, the trial will be run as double blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201703129014N151**
Registration date: **2017-03-12, 1395/12/22**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-03-12, 1395/12/22

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin D supplementation versus placebo on hypertension in patients with vitamin D deficiency: a double blind randomized clinical trial

Public title

Effect of vitamin D supplementation versus placebo on hypertension in patients with vitamin D deficiency

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age of 18 to 75 years; systolic blood pressure equal to or greater than 140 mmHg or diastolic blood pressure equal to or greater than 90 mmHg in tow times; vitamin D deficiency. Exclusion criteria: Pregnancy; secondary hypertension; renal failure; a history of using vitamin D or calcium during the last three months; using Thiazide-type diuretics.

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **208**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Therefore, the trial will be run as double blind.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2016-12-10, 1395/09/20

Ethics committee reference number

IR.UMSHA.REC.1395.393

Health conditions studied

1

Description of health condition studied

Vitamin D deficiency

ICD-10 code

E55

ICD-10 code description

Vitamin D deficiency

Primary outcomes

1

Description

Measuring systolic and diastolic blood pressure

Timepoint

before intervention and then monthly for 2 months

Method of measurement

in sitting position from the right hand using mercury sphygmomanometer

Secondary outcomes

1

Description

Measuring serum Calciferol

Timepoint

before intervention and then monthly for 2 months

Method of measurement

through laboratory test

Intervention groups

1

Description

Intervention group: Routine anti-hypertensive drugs plus gelatin tablet vitamin D (Calciferol) based on Vitamin D serum level (50,000 U once a week oral in subjects with Vitamin D serum level less than 20 ngr/mL and 1000 U in subjects with serum level between 20 to 30 ngr/mL) for 2 months

Category

Treatment - Drugs

2

Description
Control group: Routine anti-hypertensive drugs plus gelatin tablet placebo once a week for 2 months.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Farshchian Hospital
Full name of responsible person
Dr Vida Sheikh
Street address
Farshchian Heart Hospital, Shahid Fahmideh Ave.
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
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Hamadan
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 the Technology, Hamadan 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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Person responsible for updating data

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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