

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

Country

Iran (Islamic Republic of)

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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 two 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

Street address

Hamadan University of Medical Sciences, Shahid
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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

Name of organization / entity

Farshchian Heart Hospital

Full name of responsible person

Dr Vida Sheikh

Position

Nephrologist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Farshchian Heart Hospital

Full name of responsible person

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Position

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Department of Epidemiology

Full name of responsible person

Dr Jalal Poorolajal

Position

Associate Professor

Other areas of specialty/work

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empty

Sharing plan

Informed Consent Form

empty

Deidentified Individual Participant Data Set (IPD)

Clinical Study Report

empty

empty

Study Protocol

Analytic Code

empty

empty

Data Dictionary

Statistical Analysis Plan

empty