Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of vitamin D supplementation on primary hypertension: a randomized clinical trial

Protocol summary

Summary

Objective: to assess the effect of vitamin D supplementation versus no intervention on primary hypertension; Design: randomized controlled trial Setting: eligible patients with primary hypertension who refer to Ekbatan hospital in 2012 will be enrolled in the study Inclusion criteria: (a) age of 15 or greater; (b) having systolic blood pressure equal to or greater than 140 mmHg or diastolic blood pressure equal to or greater than 90 mmHg on two separate occasions. Exclusion criteria: (a) having secondary hypertension; (b) having diabetes; (c) having chronic kidney disease; (d) being pregnant; (e) history of using of vitamin D or calcium during the last three months; (f) history of using Thiazide-type diuretics. Intervention: 104 patients with primary hypertension will receive routine anti-hypertension medication plus oral soft gel of vitamin D supplementation (D3) 50,000 U one per week for three months. Control: 104 patients with primary hypertension will receive routine anti-hypertension medication for three months. Outcome: measurement of systolic and diastolic blood pressure in mmHg using mercury manometer and a stethoscope in setting position from right hand at baseline and monthly for three months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201211239014N12**
Registration date: **2012-12-01, 1391/09/11**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-12-01, 1391/09/11

Registrant information

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Jalal Poorolajal
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Recruitment status

Recruitment complete

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

Expected recruitment start date

2012-12-21, 1391/10/01

Expected recruitment end date

2013-03-19, 1391/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin D supplementation on primary hypertension: a randomized clinical trial

Public title

Effect of vitamin D supplementation on primary hypertension: a randomized clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (a) age of 15 or greater; (b) having systolic blood pressure equal to or greater than 140

mmHg or diastolic blood pressure equal to or greater than 90 mmHg on two separate occasions. Exclusion criteria: (a) having secondary hypertension; (b) having diabetes; (c) having chronic kidney disease; (d) being pregnant; (e) history of using of vitamin D or calcium during the last three months; (f) history of using Thiazide-type diuretics.

Age
From **18 years** old to **149 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)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Local human subject review board

Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City
Hamadan

Postal code
6517838695

Approval date
2012-11-20, 1391/08/30

Ethics committee reference number
D-P-35-9-3029

Health conditions studied

1

Description of health condition studied
Primary hypertension

ICD-10 code
I10

ICD-10 code description
Essential (primary) hypertension

Primary outcomes

1

Description
Systolic blood pressure in mmHg

Timepoint
at baseline and monthly for three months

Method of measurement
Using mercury manometer and a stethoscope in setting position from right hand

2

Description
Diastolic blood pressure in mmHg

Timepoint
at baseline and monthly for three months

Method of measurement
Using mercury manometer and a stethoscope in setting position from right hand

Secondary outcomes

1

Description
Systemic adverse effect such as vomoting

Timepoint
Monthly for three months

Method of measurement
Through question

2

Description
ŷstemic adverse effect such as nausea

Timepoint
Monthly for three months

Method of measurement
Through question

Intervention groups

1

Description
Routine anti-hypertension medication plus oral soft gel of vitamin D supplementation (D3) 50,000 U one per week for three months

Category
Treatment - Drugs

2

Description
Routine anti-hypertension medication for three months

Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Ekbatan Hospital
Full name of responsible person
Dr Mohsen Gharrakhani
Street address
Ekbatan Hospital, Jahad Square
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor of Research the Technology, Hamadan University of Medical Sciences
Full name of responsible person
Dr Heidar Tavilani
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor of 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
Research Center for Health Sciences and Department of Epidemiology & Biostatistics
Full name of responsible person
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http://scholar.google.com/citations?user=LDEnqk8AAAAJ&hl=en

Person responsible for updating data

Contact

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