

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 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

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

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 vomiting

Timepoint

Monthly for three months

Method of measurement

Through question

2**Description**

Systemic 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, Jihad Square

City

Hamadan

of Epidemiology & Biostatistics, School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Postal code

6517838695

Phone

+98 81 1838 0090

Fax

+98 81 1838 0509

Email

poorolajal@umsha.ac.ir

Web page address

<http://scholar.google.com/citations?user=LDEnqk8AAAJ&hl=en>

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 scientific inquiries

Contact**Name of organization / entity**

Research Center for Health Sciences and Department of Epidemiology & Biostatistics

Full name of responsible person

Dr Jalal Poorolajal

Position

Assistant Professor of Epidemiology

Other areas of specialty/work**Street address**

Research Center for Health Sciences and Department of Epidemiology & Biostatistics, School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

6517838695

Phone

+98 81 1838 0090

Fax

+98 988118380509

Email

poorolajal@umsha.ac.ir

Web page address

<http://scholar.google.com/citations?user=LDEnqk8AAAJ&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

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

Dr Jalal Poorolajal

Position

Assistant Professor of Epidemiology

Other areas of specialty/work**Street address**

Research Center for Health Sciences and Department

Clinical Study Report
empty
Analytic Code

empty
Data Dictionary
empty