

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the effect of vitamin D supplementation on different stages of blood pressure in hypertension patients with level of vitamin D under 30ng/ml

Protocol summary

Study aim

Evaluation of the effect of vitamin D supplementation on different stages of blood pressure in hypertension patients with level of vitamin D under 30ng/ml

Design

Clinical trial with control group, with parallel groups, double-blind, randomized with Stratified Block Randomization, with sample size of 116 people, phase 3 trial

Settings and conduct

Seyed Alshohada Medical Education Center in Urmia. people with hypertension and vitamin D less than 30 ng/ml enter the study. Blood pressure was measured (Ambulatory Blood Pressure Monitoring) and blood factors at baseline and end of study and physical activity, diet, sun exposure at baseline, week 6 and end of study. The participant, the clinical caregiver, the researcher, the outcome assessor have become blind and supplements are distributed by a person who is not present in the study

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18 and over, interest in study, blood pressure above 140/90, vitamin D < 30 ng/dl, only use the following four drugs to control their blood pressure: 1 - Angiotensin inhibitor 2- Calcium channel blocker 3- Beta-adrenergic receptor blocker 4- Diuretics : Exclusion criteria: secondary hypertension, certain dietary restrictions, pregnancy or lactation, non-steroidal anti-inflammatory or glucocorticoid medication, chemotherapy, use of bisphosphonates, anticonvulsant drug, medication Diarrhea hyperlipidemic, alcohol, radioactive iodine intake, corticosteroid, kidney disease, calcium, potassium, magnesium supplements

Intervention groups

Intervention and control group :hypertensive persons with vitamin D less than 30 ng/ml; intervention group receive 50000 IU vitamin D and control group will receive

placebo, one pill for each weeks until 6 weeks and then two pills for 2 months.

Main outcome variables

Weight: Serum vitamin D levels: Dietary vitamin D: sun exposure: stages of blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190819044565N1**
Registration date: **2019-09-28, 1398/07/06**
Registration timing: **registered_while_recruiting**

Last update: **2019-09-28, 1398/07/06**

Update count: **0**

Registration date

2019-09-28, 1398/07/06

Registrant information

Name

Samira Faraji

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3343 6241

Email address

farajisamira2019@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-01-20, 1398/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of vitamin D supplementation on different stages of blood pressure in hypertension patients with level of vitamin D under 30ng/ml

Public title

Evaluating the effect of vitamin D supplementation on different stages of blood pressure

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age range 18 years and above Interested in attending a study that filled out an informed consent form Hypertensive patients with systolic blood pressure above 140 and diastolic blood pressure above 90 with identical conditions and approved by the cardiologist in the study Serum vitamin D levels less than 30 ng/dl People who use only the following four drugs to control their blood pressure 1 Angiotensin Inhibitors (Losartan, Captopril, Valsartan) 2 Calcium channel blockers (amlodipine, diltiazem) 3 Inhibitors of beta-adrenergic receptors (ethanolol, metoprolol, bisoprolol (concur)) 4 Diuretics (hydrochlorothiazide, triamterene)

Exclusion criteria:

Mental, emotional, cognitive disorders People under 18 years People with secondary hypertension Specific dietary restrictions Pregnant women Nonsteroidal anti-inflammatory drugs or glucocorticoids Disease that requires chemotherapy or radiation Consumption of bisphosphonates, including alendronate, alendronate and rhizdronate Use of anticonvulsant drugs (including phenytoin, phenobarbital, primidone, carbamazepine, x carbazepine, valproic acid, clonazepam) Use of antihyperlipidemic diarrhea medications including cholestyramine Alcohol consumption Consumption of radioactive iodine or any radiation Oral or injectable corticosteroids (including prednisone, prednisilone, dexamethasone, triaxinolone, hydrocortisone or beta-metazone) Kidney diseases Calcium supplements Lactating women Coeliac disease Crohn's disease Ulcerative colitis Steatorrhea Biliary problems Potassium supplementation Magnesium Supplementation

Age

From 18 years old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: 116

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization, using Stratified Block Randomization statistical software

Blinding (investigator's opinion)

Double blinded

Blinding description

The data analyzer is aware of study group information, coding individual names, and participants, clinical caregiver, researcher, outcome assessor in this study will be kept blind to assignment to study groups, and supplements and placebo It will be distributed by someone who is not in the study.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Urmia University of Medical Sciences

Street address

Department of Nutrition, Faculty of Medicine, Urmia University of Medical Sciences, Urmia, Iran

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2019-08-26, 1398/06/04

Ethics committee reference number

IR.UMSU.REC.1398.192

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

Stages of blood pressure

Timepoint

at baseline (before intervention) and end of study (after 14 weeks)

Method of measurement

Ambulatory Blood Pressure Monitoring, millimeter mercury

Secondary outcomes

1

Description

Vitamin D from daily diet

Timepoint

At the beginning of the study (before the intervention) and at 6 and 10 weeks and at the end of the study (after 14 weeks)

Method of measurement

Food Frequency Questionnaire

2

Description

Duration of exposure to sunlight

Timepoint

At the beginning of the study (before the intervention) and at 6 and 10 weeks and at the end of the study (after 14 weeks)

Method of measurement

Sun Exposure Questionnaire

3

Description

The amount of physical activity

Timepoint

At the beginning of the study (before the intervention) and at 6 and 10 weeks and at the end of the study (after 14 weeks)

Method of measurement

International Physical Activity Questionnaire

4

Description

Weight

Timepoint

At the beginning of the study (before the intervention) and at 6 and 10 weeks and at the end of the study (after 14 weeks)

Method of measurement

Weigh measuring scales with accuracy of $0.1 \pm$ mg, kilogram

5

Description

Waist circumference

Timepoint

At the beginning of the study (before the intervention) and at 6 and 10 weeks and at the end of the study (after 14 weeks)

Method of measurement

Meter 0.1 centimetre precision

6

Description

Serum vitamin D levels

Timepoint

At the beginning of the study (before the intervention) and at the end of the study (after 14 weeks)

Method of measurement

Enzymatic method with auto analysis, nano molar per liter

Intervention groups

1

Description

Intervention group: Vitamin D at a dose of 50000 international units of six supplements, one supplement for week and then two supplements, one for monthly, by Zahravi Tabriz Company, total intervention 14 weeks

Category

Treatment - Drugs

2

Description

Control group: Six placebo supplements one supplement for week and then two supplements, one for monthly, by Zahravi Tabriz Company, total study 14 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Seyed Alshohada Medical Education Heart Center

Full name of responsible person

Behzad Rahimi Darabad

Street address

Shahrivar Samadzadeh St., 17 Shahrivar Blvd., Seyed Alshohada Medical Education Heart Center, Urmia

City

Urmia

Province

West Azarbaijan

Postal code

5718748983

Phone

+98 44 3237 5907

Email

behzadrahimi57@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Iraj Mohebbi

Street address

Resalat Blvd., Emergency Ave., Headquarters Urmia University of Medical Sciences, Deputy of Research and Building Technology, Urmia,

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3193 7224

Email

FarajiSamira2019@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Oroumia University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Samira Faraji

Position

Student of master Nutrition

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

Kowsar Dormitory, Urmia University of Medical Sciences, Sero highway, Urmia, Iran

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3275 4953

Email

FarajiSamira2019@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Samira Faraji

Position

Student of master Nutrition

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

Sero highway, Kowsar Dormitory, Urmia University of Medical Sciences, Urmia, Iran

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3275 4953

Email

FarajiSamira2019@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Samira Faraji

Position

Student of master Nutrition

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

Sero highway, Kowsar Dormitory, Urmia University of Medical Sciences, Urmia, Iran

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3275 4953

Email

FarajiSamira2019@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available