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 Statified 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

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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 pressure1Angiotensin Inhibitors (Losartan, Captopril, Valsartan)2 Calcium channel blockers (amlodipine, diltiazem)3Inhibitors of beta-adrenergic receptors (ethnolol, metoprolol, bisoprolol (concur))4Diuretics (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 ± 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
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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,
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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
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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