

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of vitamin D3 supplementation in blood pressure control in essential hypertensive patients

Protocol summary

Study aim

Effect of vitamin D supplementation in regulation of blood pressure in essential hypertensive patients

Design

This study is a single-center, prospective, open-labeled, parallel phase 3 clinical trial.

Settings and conduct

Patients who visit the Baqiyatallah Hospital Clinic, which meets the inclusion criteria, will be divided into two intervention groups, based on vitamin D level.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Essential Hypertension (Systolic pressure > 140 mmHg, Diastolic pressure > 90 mmHg) Adult patients from 18 to 65 y/o Patients under standard Anti-hypertensive agents Vitamin D serum level less than 30. Exclusion Criteria Heart Failure (LVEF<45%) Renal Failure (Creatinine>1.5mg/dl) Hepatic Failure Chronic Obstructive Pulmonary Disease (COPD): (FEV1/FVC <70%) Thyroid disorders Hyperparathyroidism Systemic infection Hypercalciurea

Intervention groups

Intervention arm 1 : 5000 U vitamin D until 8 weeks (in addition to routine anti hypertensive drugs); intervention arm 2: 1000 U vitamin D until 8 weeks (in addition to routine anti hypertensive drugs)

Main outcome variables

Systolic blood pressure Diastolic blood pressure mean arterial pressure vitamin D3 level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080901001165N57**

Registration date: **2020-05-27, 1399/03/07**

Registration timing: **retrospective**

Last update: **2020-05-27, 1399/03/07**

Update count: **0**

Registration date

2020-05-27, 1399/03/07

Registrant information

Name

Yunes Panahi

Name of organization / entity

Baqiyatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8821 1524

Email address

yunespanahi@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Chemical Injuries Research Center, Baqiyatallah University of Medical sciences

Expected recruitment start date

2014-10-23, 1393/08/01

Expected recruitment end date

2015-06-09, 1394/03/19

Actual recruitment start date

2014-10-23, 1393/08/01

Actual recruitment end date

2015-06-22, 1394/04/01

Trial completion date

2015-06-22, 1394/04/01

Scientific title

Investigating the effect of vitamin D3 supplementation in blood pressure control in essential hypertensive patients

Public title

Effect of vitamin D supplement in regulation of blood pressure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Essential Hypertension (Systolic pressure > 140 mmHg, Diastolic pressure > 90 mmHg) Adult patients from 18 to 65 y/o Patients under standard Anti-hypertensive agents Vitamin D level is less than 30.

Exclusion criteria:

Heart Failure (LVEF<45%) Renal Failure (Creatinine>1.5mg/dl) Hepatic Failure Chronic Obstructive Pulmonary Disease (COPD): (FEV1/FVC <70%) Thyroid disorders Hyperparathyroidism Systemic infection Hypercalciurea

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **200**

Actual sample size reached: **176**

Randomization (investigator's opinion)

Not 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

Baqiyatallah University of Medical Sciences

Street address

South Sheikh-Bahaei St., Mollasadra St., Vanak Sq.

City

Tehran

Province

Tehran

Postal code

1435916471

Approval date

2015-04-19, 1394/01/30

Ethics committee reference number

IR.RMSU.REC.1394.31

Health conditions studied

1

Description of health condition studied

Essential hypertension

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

Primary outcomes

1

Description

Systolic blood pressure

Timepoint

at baseline and 8 weeks after intervention

Method of measurement

Sphygmomanometer, mmHg

2

Description

Diastolic blood pressure

Timepoint

at baseline and 8 weeks after intervention

Method of measurement

Sphygmomanometer, mmHg

3

Description

Mean arterial pressure

Timepoint

at baseline and 8 weeks after intervention

Method of measurement

Sphygmomanometer, mmHg

4

Description

Vitamin D serum level

Timepoint

at baseline and 8 weeks after intervention

Method of measurement

ng/ml

Secondary outcomes

1

Description

Adverse effect of vitamin D supplement

Timepoint

8 weeks after treatment

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention arm 1 : Pearl vitamin D 50000 Unit,PO, weekly, for 8 weeks (in addition to routine anti hypertensive drugs);

Category

Treatment - Drugs

2

Description

Control group: Pearl vitamin D 1000 U, PO, daily, for 8 weeks (in addition to routine anti hypertensive drugs)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah hospital

Full name of responsible person

Yunes Panahi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Chemical Injuries Research Center, Baqiyatallah University of Medical Sciences

Full name of responsible person

Yunes Panahi

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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

Chemical Injuries Research Center, Baqiyatallah 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

Baqiyatallah University of Medical Sciences

Full name of responsible person

Javad Rostami-Yalmeh

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Chemical Injuries Research Center, Baqiyatallah University of Medical sciences

Full name of responsible person

Yunes Panahi

Position

professor

Latest degree

Specialist

Other areas of specialty/work

Pharmacotherapy

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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

Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Parisa Kianpour

Position

assistant

Latest degree

Specialist

Other areas of specialty/work

Pharmacotherapy

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