Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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
Street address
South Sheikh-Bahaei St., Mollasadra St., Vanak Sq.
City
Tehran
Province
Tehran
Postal code
1435916471
Phone
+98 21 8245 5393
Email
Yunespanahi@yahoo.com

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
Street address
South Sheikh-Bahaei St., Mollasadra St., Vanak Sq.
City
Tehran
Province
Tehran
Postal code
1435916471
Phone
+98 21 8245 5393
Email
Yunespanahi@yahoo.com
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
Street address
South Sheikh-Bahaei St., Mollasadra St., Vanak Sq.
City
Tehran
Province
Tehran
Postal code
1435916471
Phone
+98 21 8248 2516
Fax
Email
javadrostami67@yahoo.com
Web page address

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
Street address
South Sheikh-Bahaei St., Mollasadra St., Vanak Sq.
City
Tehran
Province
Tehran
Postal code
1435916471
Phone
+98 21 8248 2516
Fax
Email
yunespanahi@yahoo.com
Web page address

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
Street address
Pharmacy faculty, Tehran University of medical science, 16-Azar St., Enghelab Sq., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1417614411
Phone
+98 21 6695 4709
Email
parisa_kianpour@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