

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### The effect of vitamin D supplementation on blood pressure in hypertensive patients with vitamin D deficiency

#### Protocol summary

##### Summary

Objective: To assess the effect of vitamin D supplementation on blood pressure in hypertensive patients with vitamin D deficiency (2)Design: Parallel randomized controlled double blind trial (3)Setting and conduct: After obtaining informed consent, the patients were randomized into two groups receiving vitamin D3 or placebo using table of random numbers, blood pressure was measured and compared before and after the intervention between two groups (4)Participants including major eligibility criteria:42 hypertensive patients with vitamin D deficiency(serum 25-hydroxy vitamin D lower than 30 nmol/lit) referring to Azadshahr Health and treatment center in Yazd (Iran) (5)Intervention: Receiving 50000 IU vitamin D3 supplementation (group1) or placebo(group2) for 8 weeks(one pearl per week) (6)Main outcome measures: Hypertension

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012090310724N1**  
Registration date: **2012-09-25, 1391/07/04**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-09-25, 1391/07/04

##### Registrant information

###### Name

Saba Loloie

###### Name of organization / entity

Shahid Sadoogi University Of Medical Sciences and Health Services

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 1624 5900

##### Email address

saba.loloie@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Shahid Sadoogi University of Medical Sciences and Health Services

##### Expected recruitment start date

2012-09-23, 1391/07/02

##### Expected recruitment end date

2013-09-21, 1392/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of vitamin D supplementation on blood pressure in hypertensive patients with vitamin D deficiency

##### Public title

The effect of vitamin D supplementation on blood pressure in hypertensive patients with vitamin D deficiency

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: patients with Systolic Blood Pressure equal or more than 140 mmHg ; and Diastolic Blood Pressure equal or more than 90 mmHg. ; and serum 25-hydroxy vitamin D3 lower than 30 ng/ml ; living in Yazd province; aged 25-50 years; not to be alcohol user or smoker or addicted ; without any liver or Coronary-artery

or renal or Gastro Intestinal disorders; not using oral or injection of corticosteroids; not using cardiac glycosides or antiepileptic drugs; not using multi vitamins or supplements containing vitamin D, Calcium, Magnesium, Phosphorus or their analogs in past 3 mounts; not using injection of vitamin D in past 6 mounts; Exclusion criteria: any change in dosage or type of anti hypertension drugs; not following the study protocol. Exclusion criteria: any change in dosage or type of anti hypertension drugs; not following the study protocol.

#### Age

From **25 years** old to **50 years** old

#### Gender

Both

#### Phase

2-3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **48**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Moral Committee of Shahid Sadoogi University of Medical Sciences and Health Services

##### Street address

Bahonar sq

##### City

Yazd

##### Postal code

#### Approval date

2012-07-28, 1391/05/07

#### Ethics committee reference number

61670/1/17/پ

## 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

hypertension

#### Timepoint

before and 8 week after intervention

#### Method of measurement

mercurial sphygmomanometer

## Secondary outcomes

### 1

#### Description

serum Calcium

#### Timepoint

before and 8 weeks after intervention

#### Method of measurement

laboratory biochemical measurements

### 2

#### Description

serum 25- Hydroxy vitamin D

#### Timepoint

before and 8 weeks after intervention

#### Method of measurement

laboratory biochemical measurements \_nmol/lit

### 3

#### Description

serum PTH

#### Timepoint

before and 8 weeks after intervention

#### Method of measurement

laboratory biochemical measurements

### 4

#### Description

serum phosphorus

#### Timepoint

before and 8 weeks after intervention

#### Method of measurement

laboratory biochemical measurements

## Intervention groups

### 1

#### Description

50000IU vitamin D3 pearl(oral supplements),for 8 weeks, one pearl per week

#### Category

Treatment - Drugs

## 2

### Description

placebo pearl, for 8 weeks, one pearl per week

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

AZAD SHAHR health and treatment center of YAZD

##### Full name of responsible person

Dr Mohammadreza Mirjalili

##### Street address

Safaeie St.

##### City

Yazd

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Shahid Sadoogi University of Medical Sciences

##### Full name of responsible person

Dr Hassan Mozaffari Khosravi

##### Street address

Bahonar sq

##### City

Yazd

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Vice chancellor for research, Shahid Sadoogi 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 general inquiries

#### Contact

##### Name of organization / entity

Shahid sadoogi University Of Medical Sciences and Health Services

##### Full name of responsible person

Dr Mohammadreza Mirjalili

##### Position

specialist

##### Other areas of specialty/work

##### Street address

Bahonar sq

##### City

Yazd

##### Postal code

##### Phone

+98 35 1724 0172

##### Fax

##### Email

drmirjalili@yahoo.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shahid Sadoogi University Of Medical Sciences and Health Services

##### Full name of responsible person

Dr Hassan Mozaffari Khosravi

##### Position

PHD, nutrition

##### Other areas of specialty/work

##### Street address

Bahonar Sq

##### City

Yazd

##### Postal code

##### Phone

+98 131531467

##### Fax

##### Email

mozaffari.kh@gmail.com

##### Web page address

## Person responsible for updating data

#### Contact

##### Name of organization / entity

Shahid Sadoogi University Of Medical Sciences and Health Services

##### Full name of responsible person

Saba Loloie

##### Position

MS student of Health Sciences in Nutrition

##### Other areas of specialty/work

##### Street address

##### City

Yazd

##### Postal code

##### Phone

00

##### Fax

##### Email

saba.loloie@gmail.com

##### Web page address

## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*