

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Evaluating the effect of vitamin D on decreasing blood pressure in patients with Stage 1 hypertension

#### Protocol summary

##### Study aim

Evaluating the effect of vitamin D on decreasing blood pressure in patients with Stage 1 hypertension

##### Design

Randomized clinical trial, without control group, parallel groups, double-blind, phase 2, 80 patients, randomization with rand function of Excel software.

##### Settings and conduct

This study will be performed on patients with stage 1 blood pressure and vitamin D deficiency referred to the Golestan Hospital nephrology clinic and patients will be given 2 different doses of vitamin D in two treatment groups. In this randomization, none of the patients in the two groups and the physician will know the type and dosage of the prescribed drugs.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: serum level vitamin D between 10-30 ng/dl; having hypertension stage 1. Exclusion criteria: CKD > 1.2 mg / dL; Liver failure; Proteinuria greater than 500 mg in 24 hours; heart failure; Pregnancy; Secondary hypertension; No consumption more than 20% of the drug delivered to them.

##### Intervention groups

Patients in group A were given vitamin D at a dose of 1000 mg daily for 8 weeks. Vitamin D was manufactured by Sobhan Company from Iran. Group B was given vitamin D at a dose of 50,000 mg once a week for 8 weeks. The drugs were administered in both groups with 50 cc of water one hour before meals. Patients were also advised to follow a regular diet during the study period

##### Main outcome variables

Vitamin D levels and hypertension stage 1

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190105042238N1**

Registration date: **2020-07-25, 1399/05/04**

Registration timing: **retrospective**

Last update: **2020-07-25, 1399/05/04**

Update count: **0**

##### Registration date

2020-07-25, 1399/05/04

##### Registrant information

###### Name

reza zargoosh

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 4269 0075

###### Email address

drrezazargoosh78@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-11-11, 1398/08/20

##### Expected recruitment end date

2020-02-09, 1398/11/20

##### Actual recruitment start date

2019-11-11, 1398/08/20

##### Actual recruitment end date

2020-02-09, 1398/11/20

##### Trial completion date

2020-02-17, 1398/11/28

##### Scientific title

Evaluating the effect of vitamin D on decreasing blood pressure in patients with Stage 1 hypertension

##### Public title

effect of vitamin D on decreasing blood pressure

##### Purpose

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
serum level vitamin D between 10-30 ng/dl having hypertension stage 1

**Exclusion criteria:**  
CKD> 1.2 mg / dL Liver failure patients Proteinuria greater than 500 mg in 24 hours Patients with heart failure Pregnancy Secondary hypertension No consumption more than 20% of the drug delivered to them

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

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**  
Target sample size: **80**  
Actual sample size reached: **74**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Patients were divided into two groups A and B. Block randomization methods were used. The size of the block was four and in each block 2 patient in group A and 2 patient in group B were assigned. The order of groups A and B within each block was determined randomly using function (RAND) in Excel software.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Patients and the interventionist and the person examining the results did not know what group the individuals were in, and the study would be double blind

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

1

### Ethics committee

**Name of ethics committee**

ethics committee of Ahwaz Jundishapur University of Medical Sciences (AJUMS)

**Street address**

Khuzestan Province, Ahvaz

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135715794

**Approval date**

2019-11-10, 1398/08/19

**Ethics committee reference number**

IR.AJUMS.REC.1398.580

## Health conditions studied

1

**Description of health condition studied**

hypertension and vitamin D deficiency

**ICD-10 code**

I15

**ICD-10 code description**

Secondary hypertension

## Primary outcomes

1

**Description**

Hypertension

**Timepoint**

Before the intervention and 2 months after the intervention

**Method of measurement**

24-hour blood pressure monitoring and measurement

## Secondary outcomes

1

**Description**

Measurement of vitamin d

**Timepoint**

Before the intervention and 2 months after the intervention

**Method of measurement**

Through a laboratory test

## Intervention groups

1

**Description**

Patients in group A vitamin D at a dose of 1000 mg daily for 8 weeks

**Category**

Treatment - Drugs

2

**Description**

Intervention group: To group B, vitamin D with a dose of 50,000 mg per week for 8 weeks

**Category**

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Nephrology Clinic of Golestan Hospital in Ahvaz

**Full name of responsible person**

Dr Eisa Rezaei

**Street address**

Ahvaz, Farvardin Blvd., Golestan hospital

**City**

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**Province**

Khuzestan

**Postal code**

6135715794

**Phone**

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**Email**

Golestanjpsital@yahoo.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Dr Eisa Rezaei

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Info@Ajums.Ac.Ir

**Grant name**

Ahvaz Jundishapur University of Medical Sciences

**Grant code / Reference number**

U-98172

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

Yes

**Title of funding source**

Ahvaz 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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Dr Eisa Rezaei

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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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**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available