Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)
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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

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

Street address

Khuzestan Province, Ahvaz

City

Ahvaz

Province

Khouzestan

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

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Ahvaz, Farvardin Blvd., Golestan hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

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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