

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of vitamin D treatment on magnesium levels in chronic hemodialysis patients

Protocol summary

Study aim

The efficacy of vitamin D treatment on magnesium levels and prevention of Hypomagnesemia (serum Mg level $\leq$ 1.7 mg/dl) in chronic hemodialysis patient

Design

This is a clinical trial study with parallel groups, double-blinded randomized, will be conducted on 60 chronic hemodialysis patient. Assignment of patients to the study groups will be done by random-numbers table and using computer.

Settings and conduct

This study will be performed on chronic hemodialysis patients referring to Imam Khomeini Hospital in Ahvaz. At least 60 patients will be randomly assigned to one of two treatment groups. The patients and experimenters will not know about type of treatment and patient grouping and thus until the end of trial the study will be remained double-blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age more than 18 years, hemodialysis patients who have been on dialysis for at least three months, vitamin D level less than 30 ng/mL, consent to participate in the study; Exclusion criteria: any active or chronic infection, magnesium supplementation, chronic diarrhea, hyperparathyroidism

Intervention groups

In first group, Calcium with D3 500 mg tablets (Dineh CO., Iran) every 12 hours will be prescribed for 3 months. In the second group, oral Pearl Vit D3-50000 unit per week (Dana Pharma CO., Iran) will be prescribed for 3 months.

Main outcome variables

Serum magnesium and vitamin D levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210314050698N1**

Registration date: **2021-04-03, 1400/01/14**

Registration timing: **prospective**

Last update: **2021-04-03, 1400/01/14**

Update count: **0**

Registration date

2021-04-03, 1400/01/14

Registrant information

Name

Ebrahim Hamreh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 5222 2621

Email address

ehamreh1366@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-10-22, 1400/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin D treatment on magnesium levels in chronic hemodialysis patients

Public title

Effect of vitamin D treatment on magnesium levels in

hemodialysis patients

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Age more than 18 years Hemodialysis patients who have been on dialysis for at least three months Vitamin D level less than 30 ng/mL Consent to participate in the study
Exclusion criteria:
Any active or chronic infection Magnesium supplementation Chronic diarrhea Hyperparathyroidism

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be assigned into two groups by simple randomization method. Allocation of patients to the study groups will be done by random-numbers table and using computer, and on this basis patients will be included in one of the two treatment groups. The implementation of the random allocation sequence occurs without knowledge of which patient will receive which treatment.

Blinding (investigator's opinion)
Double blinded

Blinding description
Intervention (receiving oral Calcium with D3 500 mg Tabs or Pearl Vit D3-50000) and patient evaluation will be carried out by a physician who is blinded to placement in treatment groups. Also patients and statistical analyzer will not know about patient grouping.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.

City

Ahvaz

Province

Khouzestan

Postal code

6135733118

Approval date

2021-03-14, 1399/12/24

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1399.172

Health conditions studied

1

Description of health condition studied

Chronic hemodialysis patients

ICD-10 code

N18

ICD-10 code description

Chronic kidney disease (CKD)

Primary outcomes

1

Description

Serum magnesium level

Timepoint

Before and after treatment (three months later)

Method of measurement

Based on laboratory results measured by magnesium kit (Pars Azmoon,Iran)

2

Description

Serum vitD (25-OH-VitD) level

Timepoint

Before and after treatment (three months later)

Method of measurement

Based on laboratory results measured by Vit D kit (Monobind,Iran)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, oral Pearl Vit D3-50000 unit per week (Dana Pharma CO., Iran) will be prescribed for 3 months.

Category

Prevention

2

Description

Intervention group: In this group, Calcium with D3 500 mg tablets (Dineh CO., Iran) every 12 hours will be prescribed for 3 months.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Ebrahim Hamreh

Street address

Imam Khomeini Hospital, Azadegan St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

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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

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

Ebrahim Hamreh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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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