Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigating the effect of vitamin K supplementation on bone factors in hemodialysis patients

Protocol summary

Study aim
the effect of vitamin K supplementation on bone factors in hemodialysis patients Comparison of alkaline phosphatase level in hemodialysis patients in two groups A and B Comparison of calcium level in hemodialysis patients in two groups A and B Comparison of phosphorus level in hemodialysis patients in two groups A and B Comparison of vitamin D level in hemodialysis patients in two groups A and B

Design
A clinical trial with a control group with parallel groups, randomized using a phase 2-3 randomized block method on 72 patients with ESRD and hemodialysis. The rand function of Excel software was used for randomization.

Settings and conduct
This study will be conducted by randomized block method on ESRD patients hemodialysis referred to 5 Azar and Yad Gorgan Hospital in 2021.

Participants/Inclusion and exclusion criteria
Hemodialysis patients with the age of 18-75 years and at least one month has passed since the start of dialysis are included in the study, and at the same time, patients with the use of anticoagulant drugs, antibiotics, infection with high CRP and lack of satisfaction and non-compliance with medication The study will be deleted.

Intervention groups
Group A: Calcium-D capsule with vitamin K2 tablet (capsule containing vitamin K2-7, microcrystalline, cellulose, colloidal silicon dioxide, magnesium stearate) Group B: calcium capsule - D

Main outcome variables
The main outcome of the study:Changes of the average serum alkaline phosphatase level after the intervention

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221217056845N1**
Registration date: **2023-03-04, 1401/12/13**
Registration timing: **retrospective**

Last update: **2023-03-04, 1401/12/13**
Update count: **0**

Registration date
2023-03-04, 1401/12/13

Registrant information

Name
sedighe maghsoudloo

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 17 3246 0722

Email address
roya_sissy200@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-05, 1401/10/15

Expected recruitment end date
2023-02-04, 1401/11/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of vitamin K supplementation on bone factors in hemodialysis patients

Public title
the effect of vitamin K supplementation on bone factors

in hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Not using anticoagulant drugs age 18-75 years patient with ESRD and hemodialysis patients that dialyses > 1 months.

Exclusion criteria:

Coagulation disorder Lack of consent to study Hypocalcemia or hypercalcemia in patients Infection before and during treatment with High CRP Using of antibiotic drugs Using of osteoporosis drugs lack of medication compliance

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible patients were assigned to experimental and control groups using the random block method. For random allocation using blocks of 4, first by throwing 18 regular hexagons, a random sequence of 18 blocks of 4 was generated from among the following blocks: AABB-ABAB-ABBA-BAAB-BABA-BBAA In the desired sequence, there will be 37 of each letter A and B. According to the above block, 72 envelopes were prepared and the letter A or B was placed in each envelope and numbered from 1 to 72.

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

Ethics committee of Golestan University of Medical Sciences

Street address

Vice President of Research,Gorgan University of Medical Sciences, the beginning of Shesat Kala Rural Road,Hirkan Blvd,Basij Square

City

Gorgan

Province

Golestan

Postal code

۷۴۵۱۵ - ۴۹۳۴۱

Approval date

2022-12-16, 1401/09/25

Ethics committee reference number

IR.GOUMS.REC.1401.21

Health conditions studied

1

Description of health condition studied

Patients with ESRD undergoing hemodialysis

ICD-10 code

I12.0

ICD-10 code description

Hypertensive chronic kidney disease with stage 5 chronic kidney disease or end stage renal disease

Primary outcomes

1

Description

Comparison of the average serum levels of albumin after the implementation of the intervention

Timepoint

At the beginning of the study and 3 month later

Method of measurement

blood sample

2

Description

Comparison of the average serum levels of calcium after the implementation of the intervention

Timepoint

At the beginning of the study and 3 month later

Method of measurement

blood sample

3

Description

Comparison of the average serum levels of phosphorus after the implementation of the intervention

Timepoint

At the beginning of the study and 3 month later

Method of measurement

blood sample

4

Description

Comparison of the average serum levels of Vitamin D after the implementation of the intervention

Timepoint

At the beginning of the study and 3 month later

Method of measurement
blood sample

Secondary outcomes

1

Description
Comparison of the mean serum PTH level after the implementation of the intervention to the basic value
Timepoint
At the beginning of the study and 3 month later
Method of measurement
blood sample

2

Description
Comparison of the mean serum alkaline phosphatase (AKP) level after the implementation of the intervention to the basic value
Timepoint
At the beginning of the study and 3 month later
Method of measurement
blood sample

Intervention groups

1

Description
Intervention group: Calcium-D capsule (Shefa company contains 500 mg calcium and 200 IU vitamin D) along with vitamin K2 tablets (capsule containing vitamin K2-7, microcrystalline, cellulose, colloidal silicon dioxide, magnesium stearate) three times in daily for 8 weeks
Category
Treatment - Drugs

2

Description
Control group: They receive calcium-D capsules three times a day for 8 weeks and placebo tablets with the same packaging and shape as vitamin K2 capsules.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
5 Azar hospital
Full name of responsible person
Dr Saeid Amirkhanlou
Street address
Fifth Azar Hospital, Valiasr Square, Gorgan
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
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Street address
Gorgan University of Medical Sciences,the beginning of Shasta Kala Rural Road, Hirkan Blvd, Basij Square.
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۴۹۳۴۱۷۴۵۱۵
Phone
+98 17 3245 0021
Email
gsm@goums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

Sedighe Maghsoudloo

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Sedighe Maghsoudloo

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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

Medical doctor

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Internal Medicine

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Postal code

49178677439

Phone

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Not applicable

Title and more details about the data/document

The level of variables before and after the study / age of the patient / duration of dialysis and sex are informed

When the data will become available and for how long

Start the access period 6 months after printing results

To whom data/document is available

For researchers working in academic and scientific institutions

Under which criteria data/document could be used

request and submission of usage documentation in new studies

From where data/document is obtainable

Golestan University of Medical Sciences / Gorgan - Hirkan Blvd - Golestan University of Medical Sciences /

01732430310 / pr-5azar@goums.ac.ir

What processes are involved for a request to access data/document

The applicant will access within 1 month

Comments