Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Aug 2026

Evaluation of the relationship between Serum Levels of Total Antioxidants and Vitamin D supplementation in Hemodialysis Patients

Protocol summary

Study aim

The relationship between serum levels of total antioxidants and vitamin D supplementation will be evaluated in Hemodialysis Patients.

Design

86 dialysis patients will be included in the phase 3 of study via simple random non-probability sampling method consecutively. After that patients will randomly be divided into two similar parallel, double-blind groups of Colecalciferol and Placebo with random digits table. All data will remain private with encoding method.

Settings and conduct

In this clinical trial study, 86 dialysis patients who referred to Hemodialysis center of Tabriz university of medical sciences were randomly divided into two groups and one group will be receiving Colecalciferol and the other group receiving Placebo. The two groups will be in almost the same range in terms of diet and activity. All names and personal data of patients will encode during gathering data and will remain totally private. In addition, none of the participants will be grouped at the beginning of study.

Participants/Inclusion and exclusion criteria

Including criteria: Consent to participate in the study; Age range of 15-70 years; Dialysis patients undergoing blood dialysis for more than 3 months; Patients undergoing hemodialysis 3 times a week; Patients undergoing blood hemodialysis that their 25-hydroxyvitamin D concentration is less than 30 ng/ml. Excluding criteria: Dissatisfaction to participate in the study; Patients with active infection; Patients with history of renal transplantation; Patients with any history of malignancy; Presence of hyperphosphatemia (Blood phosphor >7); History of parathyroidectom

Intervention groups

Intervention group: Colecalciferol (50000 units per week for 12 weeks; Control group: Placebo

Main outcome variables

Evaluation of lipid profile, serum levels of 25OHD, Hemoglobin, PTH, Calcium, Phosphor, Klotho, ,MDA, CRP, and routine laboratory factors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201108049311N3**
Registration date: **2021-02-06, 1399/11/18**
Registration timing: **registered_while_recruiting**

Last update: **2021-02-06, 1399/11/18**
Update count: **0**

Registration date

2021-02-06, 1399/11/18

Registrant information

Name

Seyyedeh Mina Hejazian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3336 9331

Email address

smhjz.biotech@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-30, 1399/10/10

Expected recruitment end date

2021-12-31, 1400/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the relationship between Serum Levels of Total Antioxidants and Vitamin D supplementation in Hemodialysis Patients

Public title
Evaluation of the relationship between Serum Levels of Total Antioxidants and Vitamin D supplementation in Hemodialysis Patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Consent to participate in the study Age range of 15-70 years Dialysis patients undergoing blood dialysis for more than 3 months. Patients undergoing hemodialysis 3 times a week. Patients undergoing blood hemodialysis that their 25-hydroxyvitamin D concentration is less than 30 ng/ml.

Exclusion criteria:
Dissatisfaction to participate in the study Patients with active infection Patients with history of renal transplantation Patients with any history of malignancy Presence of hyperphosphatemia (Blood phosphor >7) History of parathyroidectomy

Age
From **15 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **86**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, randomization will be by blocking method and groups division will be perform with an equal number of patients individually. Patients will divided by random digit table. Thus, the statistical population and sample size will be determined first and they will be respectively given a code or serial number. Then, the entered codes will be selected randomly from the table. This study will be double-blinded and all participants and individuals evaluating consequences of the intervention will be unaware from the allocation of study groups. Randomly allocation concealment will also go on with the method of not determining study groups before selecting patients and included individuals will be randomly grouped after sampling in this study.

Blinding (investigator's opinion)
Double blinded

Blinding description
En All names and personal data of patients will encode during gathering data and will remain totally private. In addition, none of the participants will be grouped at the beginning of study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
Tabriz university of medical sciences, Golgasht St, Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5166614766

Approval date
2021-01-25, 1399/11/06

Ethics committee reference number
IR.TBZMED.REC.1399.1012

Health conditions studied

1

Description of health condition studied
Hemodialysis patients

ICD-10 code
R88.0

ICD-10 code description
Cloudy (hemodialysis) (peritoneal) dialysis effluent

Primary outcomes

1

Description
Evaluation of lipid profile

Timepoint
Before intervention and after medication

Method of measurement
Biochemical methods

2

Description
Evaluation of serum levels of 25OHD

Timepoint
Before intervention and after medication

Method of measurement
Biochemical methods

3

Description
Evaluation of parathyroid hormone (PTH) levels
Timepoint
Before intervention and after medication
Method of measurement
Biochemical methods

4

Description
Evaluation of Klotho levels
Timepoint
Before intervention and after medication
Method of measurement
Biochemical methods

5

Description
Evaluation of CRP levels
Timepoint
Before intervention and after medication
Method of measurement
Biochemical methods

6

Description
Evaluation of MDA levels
Timepoint
Before intervention and after medication
Method of measurement
Biochemical methods

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Colecalciferol drug of Iran Hormone Pharmaceutical Company (orally pearl and capsule-like once a week (50000 units) for 12 weeks)
Category
Treatment - Drugs

2

Description
Control group: Placebo (Orally once a week)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza hospital of Tabriz
Full name of responsible person
Dr. Hamid Taybi Khosroshahi
Street address
Imam Reza hospital, Golgasht St, Tabriz
City
تبریز
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5166614766
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+98 41 3335 2073
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drtayebikh@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Samiei
Street address
Tabriz university of medical sciences, Golgasht St, Tabriz
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Tabriz
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Postal code
5166614766
Phone
+98 41 3335 7310
Email
Samiei.moh@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Hamid Taybi Khosroshahi

Position
Professor

Latest degree
Subspecialist

Other areas of specialty/work
Nephrology

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Person responsible for scientific inquiries

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Dr. Hamid Taybi Khosroshahi

Position
Professor

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no more information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not 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