

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

The effect of vitamin D administration on bone and inflammatory indexes in hemodialysis patients

Protocol summary

Study aim

The effect of vitamin D administration on bone and inflammatory indexes in hemodialysis patients

Design

This study was a single center, randomized, double-blind, placebo-controlled trial performed Tabriz, Iran. Stable chronic hemodialysis patients attending the Imam Reza university hospital dialysis center were eligible for screening.

Settings and conduct

This study was a single center, randomized, double-blind, placebo-controlled trial performed Tabriz, Iran. Stable chronic hemodialysis patients attending the Imam Reza university hospital dialysis center were eligible for screening.

Participants/Inclusion and exclusion criteria

15-70 years hemodialysis more than 3 month 3 times per week vitamin D less than 30 ml/ng.

Intervention groups

1 allocation ratio into two groups to receive either 50,000 IU of cholecalciferol or placebo every week for 12 weeks.

Main outcome variables

administration on bone

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190921044834N1**

Registration date: **2019-12-04, 1398/09/13**

Registration timing: **retrospective**

Last update: **2019-12-04, 1398/09/13**

Update count: **0**

Registration date

2019-12-04, 1398/09/13

Registrant information

Name

hamid Tayyebikhosroshahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3337 3966

Email address

khosroshahih@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2019-06-21, 1398/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D administration on bone and inflammatory indexes in hemodialysis patients

Public title

The effect of vitamin D administration on bone and inflammatory indexes in hemodialysis patients

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

15-70 years hemodialysis more than 3 month 3 times per week vitamin D less than 30 ml/ng

Exclusion criteria:

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description

Use of application rand list 1/2

Blinding (investigator's opinion)

Double blinded

Blinding description

Double blind

Placebo

Used

Assignment

Single

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 Street
Gholghasht Street Azadi

City

Tabriz

Province

East Azarbaijan

Postal code

5732457869

Approval date

2019-08-19, 1398/05/28

Ethics committee reference number

IR.TBZMED.REC.1398.588

Health conditions studied

1

Description of health condition studied

hemodialysis patients

ICD-10 code

N00-N99

ICD-10 code description

بیماری‌های سیستم ادراری تناسلی

Primary outcomes

1

Description

Administration on bone

Timepoint

In the start of study, 84 days

Method of measurement

Factors of laboratory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: allocation ratio into two groups to receive either 50,000 IU of cholecalciferol every week for 12 weeks.

Category

Placebo

2

Description

Control group: allocation ratio into two groups to receive either 50,000 IU of placebo every week for 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam reza hospital

Full name of responsible person

Jalal etemadi

Street address

Tabriz University of Medical Sciences Street
Gholghasht Street Azadi

City

Tabriz

Province

East Azarbaijan

Postal code

5744325621

Phone

+98 41 3335 5921

Email

khosroshahih@TBZMED.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Hamid tayyebi khosroshahi

Street addressTabriz University of Medical Sciences Street
Gholghasht Street Azadi**City**

Tabriz

Province

East Azarbaijan

Postal code

5974324466

Phone

+98 41 3335 5921

Email

khosroshahih@TBZMED.ac.ir

Web page address**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

Hamid tayyebi khosroshahi

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street addressTabriz University of Medical Sciences Street
Gholghasht Street Azadi**City**

Tabriz

Province

East Azarbaijan

Postal code

5974324466

Phone

+98 41 3335 5921

Email

khosroshahih@TBZMED.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Hamid tayyebi khosroshahi

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street addressTabriz University of Medical Sciences Street
Gholghasht Street Azadi**City**

Tabriz

Province

East Azarbaijan

Postal code

5974324466

Phone

+98 41 3335 5921

Email

khosroshahih@TBZMED.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Hamid tayyebi khosroshahi

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street addressTabriz University of Medical Sciences Street
Gholghasht Street Azadi**City**

Tabriz

Province

East Azarbaijan

Postal code

5974324466

Phone

+98 41 3335 5921

Email

khosroshahih@TBZMED.ac.ir

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