

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

effect of vitamin D on sleep quality in hemodialysis patients

Protocol summary

Study aim

Effect of vitamin D on sleep quality in hemodialysis patients

Design

This study is a clinical trial that is performed as before and after study(pre-test and post-test) on 30 hemodialysis patients.The study will not be blinded

Settings and conduct

First, serum level of vitamin D measured by ELISA in the morning venous blood sample. Then we complete the Pittsburg Sleep Quality questionnaire for patients with vitamin D deficiency.30 patients with vitamin D deficiency and poor sleep quality are included in this study. Because of complication of vitamin D deficiency in hemodialysis patients and ethical considerations, all patients with vitamin D deficiency will be treated ,And so, this is a before and after study .Confounding factors were controlled. Patients will treated with 50000 units of pearl vitamin D 3/week during 12 weeks. Serum 25 (OH) vitD levels and PSQI scores will be measured after treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria:age older than 18 years; undergoing dialysis for at least 3 months;hemodialysis adequacy more than1.2 (KT/V>1/2); serum vitamin D level (25(OH)vit D) less than 30 ng/ml and Pittsburgh Sleep Quality Index (PSQI)more than 5. Exclusion criteria:history of hospital admission in past 4 weeks;Psychiatric disorder (clinical diagnosis and or previous treatment); drug or alcohol abuse or smoking; patients with habits such as drinking coffee or tea before sleep.

Intervention groups

hemodialysis patients with 25(OH)VitD deficiency and poor sleep quality who are treated with 50000 unit vitamin D per week for 12 weeks.

Main outcome variables

sleep quality of hemodialysis patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200223046593N1**

Registration date: **2020-04-11, 1399/01/23**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-11, 1399/01/23**

Update count: **0**

Registration date

2020-04-11, 1399/01/23

Registrant information

Name

Maryam Namakchian Namakin

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4411 9866

Email address

m.namakchian00@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-04-18, 1399/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

effect of vitamin D on sleep quality in hemodialysis

patients

Public title
effect of vitamin D on sleep quality in hemodialysis patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
age older than 18 years, undergoing dialysis for at least 3 months, hemodialysis adequacy more than 1.2, serum vitamin D level less than 30 ng/ml and Pittsburgh Sleep Quality Index (PSQI) more than 5
Exclusion criteria:
history of hospital admission in past 4 weeks, psychiatric disorder (clinical diagnosis and or previous treatment), drug or alcohol abuse or smoking, patients with habits such as drinking coffee or tea before sleep

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshi University of Medical Sciences

Street address

Shahid Chamran Highway, Yemen Street, next to Taleghani Hospital, Shahid Beheshti University Medical Sciences

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2019-04-19, 1398/01/30

Ethics committee reference number

IR.SBMU.RETECH.REC.1397.1277

Health conditions studied

1

Description of health condition studied

Sleep quality in hemodialysis patients, after treatment of 25(OH) D deficiency

ICD-10 code

N18.5 ,

ICD-10 code description

Chronic kidney disease, stage 5 , Vitamin D deficiency

Primary outcomes

1

Description

Pittsburg Sleep Quality score

Timepoint

Pittsburg Sleep Quality score in hemodialysis patients with vitamin D deficiency, before treatment and after 12 weeks.

Method of measurement

Pittsburg Sleep Quality questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: hemodialysis patients with vitamin D deficiency (less than 30ng/ml) and poor sleep quality (Pittsburgh Sleep Quality Index more than 5) will be treated with 50000 units vitamin D per week for 12 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman Hakim hospital

Full name of responsible person

Maryam Namakchian Namakin

Street address

Loghman Hakim Hospital, Kamali Street, South Karegar Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Clinical Research Development Unit of Loghman
Hakim Hospital, Shahid Beheshti University of Medical

Full name of responsible person
Afshin Zarghi

Street address
Clinical Research Development Unit of Loghman
Hakim Hospital, Shahid Beheshti University of Medical
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1333631151

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Email
lcrdc@sbmu.ac.ir

Grant name

Grant code / Reference number
14843

**Is the source of funding the same sponsor
organization/entity?**
Yes

Title of funding source
Clinical Research Development Unit of Loghman Hakim
Hospital, Shahid Beheshti University of Medical

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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Maryam Namakchian Namakin

Position
resident

Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
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Person responsible for updating data

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Fax**Email**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

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

Undecided - It is not yet known if there will be a plan to

make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

data of sleep quality Questionnaire and serum vitamin D levels before and after treatment are shared

When the data will become available and for how long

From September 22 to November 20, 2020

To whom data/document is available

researchers OF academic and scientific institutions

Under which criteria data/document could be used

Study title and purpose of the study should be clear The proposal has been written and approved The location of the study and the names of all study researchers should be disclosed

From where data/document is obtainable

E.mail:m.namakchian00@gmail.com

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

Email their request with the title of the study.The data ,will be sent within two weeks.

Comments