

# 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  
**City**  
Tehran  
**Province**

Tehran  
**Postal code**  
1333625445  
**Phone**  
+98 21 5541 9005  
**Email**  
m.namakchian00@gmail.com

## 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  
Sciences, Kamali Street, South Karegar Avenue

**City**  
Tehran

**Province**  
Tehran

**Postal code**  
1333631151

**Phone**  
+98 21 5102 5182

**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  
**Street address**  
Loghman Hakim Hospital, Kamali Street, South  
Karegar Avenue

**City**  
Tehran

**Province**  
Tehran

**Postal code**  
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**Phone**  
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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences

**Full name of responsible person**  
Maryam Namakchian Namakin

**Position**  
resident

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## Person responsible for updating data

#### 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

**Street address**  
Loghman Hakim Hospital, Kamali Street, South Karegar  
Avenue

**City**

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**Province**

Tehran

**Postal code**

1333625445

**Phone**

+98 21 4411 9866

**Fax****Email**

m.namakchian00@gmail.com

**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**