Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 icluded 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 criterria: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 qestionnaire

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 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
1333625445
Phone
009821 55419005-11
Email
m.namakchian00@gmail.com

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
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
13333625445
Phone
009821 55419005-11
Email
m.namakchian00@gmail.com

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
تهران - مركزي
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