Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

The effect of vitamin D supplementation on seizure frequency, mental health parameters, metabolic and genetic profiles in patients with epilepsy

Protocol summary

Study aim

The aim of this study is to determine the effects of vitamin D supplementation on seizure frequency, mental health parameters, metabolic and genetic profiles in patients with epilepsy.

Design

Study design: Randomized double-blind placebo-controlled trial. Randomization will be done by the use of computer-generated random numbers. Patients will be assigned into two groups to receive vitamin D supplement (n=45) or placebo (n=45).

Settings and conduct

Among patients with epilepsy referred to Shahid Beheshti Clinic affiliated to Kashan University of Medical Sciences, 90 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Supplements and placebos are similar in shape and size. Fasting blood samples will be taken at baseline and 12 weeks after the intervention. At the beginning and the end of the intervention: 12 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 9 to 18 years and diagnosed with epilepsy; Individuals have vitamin D insufficiency and deficiency. Non-inclusion criteria: History of liver diseases; History of renal insufficiency; metabolic disorders; infectious diseases; autoimmune diseases; Taking vitamin D and other antioxidant supplements in the last 3 months and during the study.

Intervention groups

Intervention group: 50000 IU vitamin D (Zahravi, Tabriz, Iran), every 2 weeks, for 12 weeks orally. Control group: Placebo (Barij Essence, Kashan, Iran), every 2 weeks, for 12 weeks orally.

Main outcome variables

Outcomes: Beck depression inventory and the frequency of seizures (primary outcomes) and biomarkers of inflammation; oxidative stress; lipid profiles; markers of insulin metabolism; gene expression related to inflammation and insulin (secondary outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170420033551N5**
Registration date: **2019-07-02, 1398/04/11**
Registration timing: **retrospective**

Last update: **2019-07-02, 1398/04/11**
Update count: **0**

Registration date

2019-07-02, 1398/04/11

Registrant information

Name

Amir Ghaderi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-03, 1397/11/14

Expected recruitment end date

2019-03-05, 1397/12/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D supplementation on seizure frequency, mental health parameters, metabolic and genetic profiles in patients with epilepsy

Public title

The effect of vitamin D supplementation in treatment of patients with epilepsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients diagnosed with epilepsy Individuals aged 9 to 18 years vitamin D insufficiency or deficiency (serum 25-hydroxyvitamin D <30 ng/mL)

Exclusion criteria:

History of acute or chronic liver diseases History of renal insufficiency metabolic disorders infectious diseases autoimmune diseases hematologic disorders Taking vitamin D, calcium, and other antioxidant supplements in the last 3 months and during the study

Age

From **9 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

To decrease potential confounding effects, all participants will have stratified randomization according to gender (male vs. female), type of seizures (tonic-clonic vs. partial) and circulating levels of vitamin D at baseline (<15 vs. 15-29.9 ng/mL). Then, participants in each block will be randomly allocated into two treatment groups to take either supplements or placebo. Randomization will be done by the use of computer software.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the neurology clinic, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of supplements.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of National Institute for Medical Research Development of Iran (NIMAD)

Street address

National Institute for Medical Research Development of Iran, Fatemi Avenue, Tehran

City

Tehran

Province

Tehran

Postal code

1419693111

Approval date

2019-02-02, 1397/11/13

Ethics committee reference number

IR.NIMAD.REC.1398.014

Health conditions studied

1

Description of health condition studied

Epilepsy and recurrent seizures

ICD-10 code

G40

ICD-10 code description

Epilepsy and recurrent seizures

Primary outcomes

1

Description

Beck depression inventory

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Questionnaire

2

Description

the frequency of seizures

Timepoint

At the beginning of the study and after 12 weeks of

intervention
Method of measurement
checklist

Secondary outcomes

1

Description
Beck anxiety inventory
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Questionnaire

2

Description
Hs-CRP
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

3

Description
Nitric oxide
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

4

Description
Total antioxidant capacity
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

5

Description
Total glutathione
Timepoint
At the beginning of the study and 12 weeks after intervention
Method of measurement
Spectrophotometry

6

Description
Malondialdehyde
Timepoint
At the beginning of the study and 12 weeks after intervention
Method of measurement
Spectrophotometry

7

Description
Fasting plasma glucose
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

8

Description
Insulin
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

9

Description
HDL
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

10

Description
Total cholesterol
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

11

Description
Triglycerides
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

12

Description
Expressed levels of IL-1 gene
Timepoint
At the beginning of the study and 12 weeks after intervention
Method of measurement
RT-PCR

13

Description
Expressed levels of IL-6 gene
Timepoint
At the beginning of the study and 12 weeks after intervention
Method of measurement
RT-PCR

14

Description
Expressed levels of TNF-a gene
Timepoint
At the beginning of the study and 12 weeks after intervention
Method of measurement
RT-PCR

15

Description
Expressed levels of PPAR-γ
Timepoint
At the beginning of the study and 12 weeks after intervention
Method of measurement
RT-PCR

Intervention groups

1

Description
Intervention group: 50000 IU vitamin D (Zahravi, Tabriz, Iran), every 2 weeks, for 12 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo (Barij Essence, Kashan, Iran), every 2 weeks, for 12 weeks orally.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Clinic
Full name of responsible person
Dr. Ebrahim Kouchaki
Street address
Ghotbe Ravandi Boulevard, Kashan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
National Institute for Medical Research Development of Iran (NIMAD)
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
Kashan University of Medical Sciences
Full name of responsible person
Amir Ghaderi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work

Ph.D of addiction

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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