

# 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)

##### Phone

+98 918 771 7435

##### Email address

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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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Kashan

**Province**

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**Phone**

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**Email**

kouchaki.eb@gmail.com

## **Sponsors / Funding sources**

### **1**

**Sponsor****Name of organization / entity**

National Institute for Medical Research Development of Iran (NIMAD)

**Full name of responsible person**

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malek@tums.ac.ir

**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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**Person responsible for scientific inquiries**

**Contact**

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**Full name of responsible person**

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**Latest degree**

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**Contact**

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**Full name of responsible person**

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**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Ph.D of addiction

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ghaderi-am@kaums.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