

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 2026

### Effect of Vitamin D3 on seizure attacks in the patients with drug-resistant epilepsy compared with the control group

#### Protocol summary

##### Study aim

An investigation of the effect of Vitamin D3 on seizure attacks in the patients with drug-resistant epilepsy compared with the control group

##### Design

A randomized, single-blind, placebo-controlled, community-based clinical trial

##### Settings and conduct

This study is an analytical and single-blind clinical trial. It took place at Al-Zahra Medical Training Center from 2018 to 2019. Subjects of the present study were selected from patients with refractory epilepsy referred to educational hospitals and epilepsy clinics of Isfahan based on inclusion criteria. After preliminary tests, 116 patients were finally selected according to the study criteria. The control and control groups were 22 patients (11 males and 11 females respectively).

##### Participants/Inclusion and exclusion criteria

The inclusion criteria are drug resistant epilepsy and vitamin D deficiency, which is diagnosed on the basis of the doctor's opinion. Exclusion criteria are: Patients' unwillingness to continue to participate in research and other diseases that may cause problems in the research process.

##### Intervention groups

22 patients with refractory epilepsy received placebo at Isfahan Pharmacy School for 8 weeks and once a week and 22 patients with refractory epilepsy treated with Pearl Vitamin D3 for 50 weeks. They were assigned once a week.

##### Main outcome variables

The effect of vitamin D3 on the control of drug-resistant epileptic seizures was investigated.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130730014217N2**

Registration date: **2020-02-22, 1398/12/03**

Registration timing: **retrospective**

Last update: **2020-02-22, 1398/12/03**

Update count: **0**

##### Registration date

2020-02-22, 1398/12/03

##### Registrant information

###### Name

Mohammad Reza Najafi

###### Name of organization / entity

Isfahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3627 3910

###### Email address

najafi@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-04-04, 1397/01/15

##### Expected recruitment end date

2019-03-11, 1397/12/20

##### Actual recruitment start date

2018-10-22, 1397/07/30

##### Actual recruitment end date

2019-04-04, 1398/01/15

##### Trial completion date

2019-08-21, 1398/05/30

##### Scientific title

Effect of Vitamin D3 on seizure attacks in the patients with drug-resistant epilepsy compared with the control group

**Public title**

The efficacy of Vitamin D3 on seizure attacks in the patients with drug-resistant epilepsy

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

drug-resistant epilepsy to treatment No other disease  
Vitamin D3 deficiency Adult population over 18 years.

**Exclusion criteria:**

Patient's unwillingness and conscious dissatisfaction

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

Actual sample size reached: **44**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The simple randomized blocking method was performed among patients with epilepsy referred to teaching hospitals and epilepsy clinics in Isfahan individually. SPSS software was used for this purpose.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Patients were first invited and interviewed about the research and written consent was obtained. Patients were unaware of which group they were in, and they only took the prescribed medication. But the researcher knew which patient group he was in.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Isfahan University of Medical Sciences

**Street address**

Ethics Committee of Isfahan University of Medical Sciences, Isfahan University of Medical Sciences, Hezar jrib street, Isfahan, Iran

**City**

Isfahan

**Province**

Isfahan

**Postal code**

7346181746

**Approval date**

2017-03-02, 1395/12/12

**Ethics committee reference number**

IR.MUI.REC.1395.3.015

**Health conditions studied****1****Description of health condition studied**

drug-resistant epilepsy

**ICD-10 code**

G40.211

**ICD-10 code description**

Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, with status epilepticus

**Primary outcomes****1****Description**

number of seizures

**Timepoint**

At beginning and 1, 2 and 3 months after treatment, patients were visited and the number and duration of seizures occurred.

**Method of measurement**

Blood test and evaluation of 25OH vitamin D

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Control group: 22 patients with refractory epilepsy who received placebo at the Faculty of Pharmacy of Isfahan for 8 weeks and once a week.

**Category**

Placebo

**2****Description**

Intervention group: Twenty-two patients with refractory epilepsy who were treated with Pearl Vitamin D3 for fifty thousand units weekly for 8 weeks.

**Category**

Treatment - Drugs

**Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

Alzahra Hospital

**Full name of responsible person**

Mohammadreza Najafi

**Street address**

Sofe Bolvar

**City**

Esfahan

**Province**

Isfahan

**Postal code**

81746775731

**Phone**

+98 31 3620 2020

**Email**

alzahra@mui.ac.ir

**Web page address**

<http://alzahra.mui.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mohammadreza Najafi

**Street address**

Hezarjarib ST.

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**Postal code**

8174673461

**Phone**

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**Email**

najafi@med.mui.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Esfahan University of Medical Sciences

**Proportion provided by this source**

80

**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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mohammadreza Najafi

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Neurology

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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Professor

**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

professor

**Latest degree**

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**Other areas of specialty/work**

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**Email**

najafi@med.mui.ac.ir

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Patients' personal information.

**Study Protocol**

Yes - There is 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**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is 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

**Title and more details about the data/document**

The results of the analysis are shared with the reduction of seizures after vitamin D3 administration.

**When the data will become available and for how long**

Starting access after printing results

**To whom data/document is available**

Everyone can access the results of data analysis.

**Under which criteria data/document could be used**

Everyone can access the results of data analysis.

**From where data/document is obtainable**

Journal site

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

Refer to the journal's website

**Comments**