

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

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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

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Sofe Bolvar

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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

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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

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 updating data

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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