Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of effect of vitamin E on the seizure frequency and EEG findings and biochemical parameters of interactive epileptic patients treating with carbamazpin,sodium valproate and levetiracetam

Protocol summary

Summary

Epilepsy is one of the common neurological disorders characterized. Vitamin E is a natural antioxidant without any significant complication which is easily used. This study aimed to evaluate the effect of this vitamin on decreased frequency of seizure and biochemical parameter and EEG finding and increasing the effects of anti epileptic drugs. This double-blind(Blinding was performed for patients as well as researchers), random placebo-controlled clinical trial have been done on 66 patients with epilepsy treated with anti epileptic drugs referred to Kashani hospital and private clinics in Isfahan. random sampling 33 patients were allocated to intervention and control groups. The intervention group was given daily supplements of 400 IU vitamin E and the control group gave similar pills of vitamin E as placebo. Seizure frequency monthly and EEG and blood biochemical markers were measured at beginning and end of sixth months. Inclusion criteria:Age 20-50 years ;Agreed to participate in study ; Had intractable seizure ; Family will able to count the patient seizure ; Over the past two months, the patient is taking at least one of the studied drugs ;Did not use Vit E in 6 month ago ; Lack of liver and kidney failure. Exclusion criteria: No satisfaction to participant in study

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015121925595N1**
Registration date: **2016-02-06, 1394/11/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-02-06, 1394/11/17

Registrant information

Name

Fataneh Gholami Motlagh

Name of organization / entity

Isfahan Medical univercity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Isfahan University of Medical Sciences

Expected recruitment start date

2016-01-05, 1394/10/15

Expected recruitment end date

2016-01-21, 1394/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effect of vitamin E on the seizure frequency and EEG findings and biochemical parameters of interactive epileptic patients treating with carbamazpin,sodium valproate and levetiracetam

Public title

Effect of Vitamin E on Seizure

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: age 20-50; satisfaction to participant in study; intractable seizure1)two seizure in month2)use two anti epileptic drug in 6 month ago at least; family can count frequency of seizure; use one of the carbamazpine or Na valproat or levetiracetam or combination in 2 month ago;did not use vit E in 6 month ago ;don't have renal or liver failure exclusion criteria: no satisfaction to participant in study

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan Univercity of Medical Science

Street address

Azadi square, Hezar jarib avn, Isfahan.

City

Isfahan

Postal code

81746-73461

Approval date

2015-02-18, 1393/11/29

Ethics committee reference number

394186

Health conditions studied

1

Description of health condition studied

Seizure

ICD-10 code

G40

ICD-10 code description

Seizure

Primary outcomes

1

Description

Frequency of seizure

Timepoint

Once a month

Method of measurement

Ask of family patient

2

Description

Evaluation of biochemical blood

Timepoint

Beginning and end of study(6 month away)

Method of measurement

Check the total anti oxidant capacity and oxidative of sample blood(microgram/mililiter)

3

Description

EEG finding

Timepoint

Beginning and end of study(6 month away)

Method of measurement

Comparison the EEG and evaluation change of epileptiform discharge

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Vit E 400 ml daily for six month

Category

Treatment - Drugs

2

Description

Control group: 400 milligram placebo daily for six month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Personal Office
Full name of responsible person
Dr. Jafar Mehvari
Street address
Amadegah Ave.
City
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2

Recruitment center
Name of recruitment center
kashani Hospital
Full name of responsible person
Dr. Mohammad Zare
Street address
Kashani Ave.
City
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3

Recruitment center
Name of recruitment center
Personal Office
Full name of responsible person
Dr. Mohammad Zare
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahanl Univercity Of Medical Science
Full name of responsible person
Vice chancellor for research,Isfahan University of Medical Sciences
Street address
Hezar Jarib Avu.,Azadi Sq.
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahanl Univercity Of Medical Science
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty