

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Evaluation of the vitamin E effect on oxidative stress markers of proteins and lipids in children with idiopathic epilepsy

#### Protocol summary

##### Summary

We studied the effect of vitamin E as an antioxidant on oxidative stress markers such as Malone dialdehyde (MDA) and protein carbonyl (PC) in 30 idiopathic epilepsy children aged 2-14 years with vitamin D deficiency. The patients were divided to two groups. One group treated with 50000 unit vitamin D for 8 weeks and the other was treated with 100 unit vitamin E daily plus 50000 unit vitamin D for 8 weeks. Inclusion criteria: having idiopathic epilepsy According to the International Association; Having vitamin D deficiency; not taking vitamin E and D In the past two months Exclusion criteria: Having a history of allergy to drugs; Any underlying systemic disease that prevent Medications; stricken Symptomatic epilepsy; stricken Mental retardation

#### General information

##### Acronym

Epilepsy therapy

##### IRCT registration information

IRCT registration number: **IRCT2013041713051N1**

Registration date: **2015-09-07, 1394/06/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-09-07, 1394/06/16

##### Registrant information

###### Name

Javad Mohiti Ardekani

###### Name of organization / entity

Yazd University of Medical Sciences

###### Country

Iran (Islamic Republic of)

##### Phone

+98 35 1820 3410

##### Email address

mohiti@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shahid Sadoughi University of Medical Sciences

##### Expected recruitment start date

2013-06-23, 1392/04/02

##### Expected recruitment end date

2014-12-23, 1393/10/02

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the vitamin E effect on oxidative stress markers of proteins and lipids in children with idiopathic epilepsy

##### Public title

The effect of vitamin E on Epilepsy

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

The study population included all children 14-2 years old that have been referred to pediatric neurology clinic of Yazd University of Medical Sciences. After taking a history and doing a physical examination and a specialty based on clinical judgment nervous children with idiopathic epilepsy were selected. Inclusion criteria: having idiopathic epilepsy According to the International Association; Having vitamin D deficiency; not taking vitamin E and D In the past two months Exclusion criteria: Having a history of allergy to drugs; Any underlying systemic disease that prevent Medications;

strickening Symptomatic epilepsy; strickening Mental retardation

#### Age

From **2 years** old to **14 years** old

#### Gender

Both

#### Phase

2

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **30**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Medical Science, Shahid Sadughi University of Medical Sciences

##### Street address

Shahid Sadughi University of Medical sciences, Bahonar St. Yazd

##### City

yazd

##### Postal code

#### Approval date

2015-04-22, 1394/02/02

#### Ethics committee reference number

IR.SSU.MEDICINE.REC.1393.102

## Health conditions studied

### 1

#### Description of health condition studied

Epilepsy

#### ICD-10 code

G40.3

#### ICD-10 code description

Generalized idiopathic epilepsy and epileptic syndromes

## Primary outcomes

### 1

#### Description

Malone dialdehyde

#### Timepoint

Before Intervention and two months after that

#### Method of measurement

Spectrophotometry

### 2

#### Description

carbonyl group

#### Timepoint

Before Intervention and two months after that

#### Method of measurement

Spectrophotometry

## Secondary outcomes

### 1

#### Description

The number of seizures

#### Timepoint

Before intervention and two months after that

#### Method of measurement

Questionnaire

## Intervention groups

### 1

#### Description

The first group(control) was treated with oral capsules of 50000 units weekly, for 8 weeks

#### Category

Treatment - Drugs

### 2

#### Description

the second group(intervention) was treated with oral capsules of 50000 units weekly, for 8 weeks and pill of 100 IU vitamin E for a month

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Yazd Shahid Sadughi Hospital

##### Full name of responsible person

Sona Rezaei

##### Street address

Shahid Sadughi Hospital, Shahid Ghandi Street

##### City

Yazd

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Shahid Sadoughi University of Medical Sciences

**Full name of responsible person**

Amirhoushang Mehrparvar

**Street address**

Shahid Sadoughi University of Medical sciences,  
Bahonar St. Yazd

**City**

yazd

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahid Sadoughi University of Medical Sciences

**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

**Name of organization / entity**

Shahid Saddoughi University of Medical Sciences

**Full name of responsible person**

Dr. Javad Mohiti

**Position**

Ph.D, Biochemistry

**Other areas of specialty/work**

**Street address**

Faculty of Medicine, Pardis University, Shahid bahonar  
Street,

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**Web page address**

## Person responsible for scientific inquiries

### Contact

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**Position**

Ph.D

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahid Sadugi University of Medical Sciences

**Full name of responsible person**

Sona Rezaei

**Position**

MS.c

**Other areas of specialty/work**

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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*