

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Evaluation of chargeable amino acids effects on intractable epileptic patients

#### Protocol summary

##### Summary

Epilepsy is one of the most common and chronic disease of central nervous system. Prevalence of epilepsy is 0.5-1/100 populations. Despite the recent developments in treatment of epilepsy and use new antiepileptic drugs, suggested more than 50 million populations of world have active epilepsy. Between 20-30% of patients don't have a good response to drugs. The aim of this study is better control of intractable epilepsy by foods (add chargeable amino acids). I will evaluate the effects of Glutamic acid, lysine and arginine ( 3 time of daily need) at mornings for two weeks. Inclusion criteria's are the epileptic patients which didn't response to anti convulsant drugs , at least passed one year after diagnosis, the patients selected who have 2-3 seizure per week despite used anticonvulsant drugs (poly therapy) and the end signed the consent form . Exclusion criteria are: The patients have other disorder, pregnant women, viral infections, side effects and non-compliant patients. The frequency of seizure calculate by patients or one of family member every day, and then compared the number of attacks one week before starting, first week after starting and second week after starting. The data analyzed descriptively and some findings have compared by T test.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201112178436N1**  
Registration date: **2012-03-03, 1390/12/13**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-03-03, 1390/12/13

#### Registrant information

##### Name

Hossein Ali Ebrahimi

##### Name of organization / entity

Neurology Research Center

##### Country

Iran (Islamic Republic of)

##### Phone

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#### Recruitment status

##### Recruitment complete

#### Funding source

Kerman University of Medical Sciences

#### Expected recruitment start date

2012-02-01, 1390/11/12

#### Expected recruitment end date

2013-02-01, 1391/11/13

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Evaluation of chargeable amino acids effects on intractable epileptic patients

#### Public title

Evaluation of chargeable amino acids effects on intractable epileptic patients

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criterion: all epileptic patients that do not have any response to antiepileptic drug. Exclusion criteria: pregnant women; lactating women; history of psychiatric diseases; viral infection and other serious diseases.

**Age**

No age limit

**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)**

Single blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

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

empty

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

Vice Chancellor of research - Kerman University of medical sciences

**Street address**

Jahad Cross way

**City**

Kerman

**Postal code****Approval date**

2011-12-21, 1390/09/30

**Ethics committee reference number**

90/373/K

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

Epilepsy

**ICD-10 code**

G40

**ICD-10 code description**

Epilepsy

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

Epileptic attacks

**Timepoint**

Two weeks

**Method of measurement**

Number of attacks

**Secondary outcomes****1****Description**

The number of seizure attacks

**Timepoint**

For three weeks ( one before and one in first week an other in second week)

**Method of measurement**

The number of seizure attacks reported by patients or family

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

Group 3 (10patients) recived Arginine (three times of daily needs) for two weeks before breakfast.

**Category**

Treatment - Drugs

**2****Description**

Intractable epileptic patients have studded. Group 1(10 patients) recieved Glutamic acid (Three times of daily needs) for two weeks every morning before breakfast .

**Category**

Other

**3****Description**

Group 2 (10 patients) recived Lyzine (three times of daily needs) for two weeks befor break fast

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shafa Medical Center

**Full name of responsible person**

Dr Hossein Alli Ebrahimi

**Street address**

Bldv. Kosar

**City**

Kerman

**2****Recruitment center**

**Name of recruitment center**  
Dr. Hossein Ali Ebrahimi Office  
**Full name of responsible person**  
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**City**  
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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Neurology Research Center  
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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**  
Neurology Research Center  
**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*