Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of L-arginine on patiant with refractory epilepsy

Protocol summary

Summary

Epilepsy is one of the world's most common non-transmissible disorders. Estimated 50 million persons are involved worldwide. Nearly 20-30% of these patients do not show desirable responses to antiepileptic drugs. In Kerman, 8/1000 populations need to use antiepileptic drugs. This study was aimed at investigating the effects of L-Arginine on the frequency and duration of attacks for refractory epileptic patients (two epileptic attacks every month after combination therapy by 2 or more antiepileptic drugs, simultaneously). Method: this study is double blind. Subsequent to obtaining informed consent, the patients were randomly divided into the two groups of intervention and control (21 subject to each group); the interventional group received l-arginine pills, twice the daily requirement, for three months, and the control group received pills containing starch, molded similar to l-arginine pills, as placebo for three months. Neither the patients nor the attending physician knew which patient received l-arginine or starch pills. The number and intensity (duration) of attacks were questioned from the patient or his/her carer and recorded in the specifically prepared questionnaire, once prior to taking the medicine or placebo, and again during treatment. After three months, the data, including seizure frequency was analyzed. The Adverse effects was also analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201603078436N3**
Registration date: **2016-04-29, 1395/02/10**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-04-29, 1395/02/10

Registrant information

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Name of organization / entity
Neurology Research Center
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Recruitment status

Recruitment complete

Funding source

Neurology Research Center - Kerman University of Medical Sciences

Expected recruitment start date

2016-04-02, 1395/01/14

Expected recruitment end date

2017-01-18, 1395/10/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of L-arginine on patiant with refractory epilepsy

Public title

Effect of L arginine on epilepsy

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion : patients with epilepsy who have not responses to combination therapy(at least 2 attack per month) by antiepileptic drugs (at least 2 drugs); Exclusion: any disorders except epilepsy; Neurologic disorder except epilepsy; Pregnancy; hypersensitivity or adverse events

to L-rrginine

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **42**

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

Kerman University of Medical Sciences

Street address

Jomhory Eslami Blvd

City

Kerman

Postal code

Approval date

2016-01-21, 1394/11/01

Ethics committee reference number

IR.kmu.REC.1394.515

Health conditions studied

1

Description of health condition studied

epilepsy

ICD-10 code

G40

ICD-10 code description

Primary outcomes

1

Description

Number of epileptic attacks

Timepoint

Duration of every attack in one month

Method of measurement

number

2

Description

severity of attacks

Timepoint

duration every attack

Method of measurement

number

Secondary outcomes

1

Description

non-tolerance

Timepoint

3 months

Method of measurement

report

Intervention groups

1

Description

L-arginine 2 size of daily need every day for three months

Category

Treatment - Drugs

2

Description

placebo(starch) 3-6 tablets every day for three months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Medical Center + Neurologic clinic of Kerman University of medical sciences

Full name of responsible person

Habibeh Mola Mohammadi

Street address

Kosar Blvd

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Neurology Research Center Kerman University of Medical Sciences
Full name of responsible person
Elham Khadir
Street address
Kosar Blvd.
City
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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 Kerman 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

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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