

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Clinical trial of the effect of folate supplementation compared with the placebo on carotid intima-media thickness and metabolic profiles in patients with epilepsy

Protocol summary

Study aim

The aim of this study is to determine the effects of folate supplementation on carotid intima-media thickness and metabolic profiles in patients with epilepsy.

Design

Study design: Parallel double-blind (both patients and researchers) clinical trial. Randomization will be done by the use of computer-generated random numbers.

Settings and conduct

Population and sample size: Among patients with epilepsy referred to Naghavi Clinic affiliated to Kashan University of Medical Sciences, 54 patients will be selected according to inclusion and exclusion criteria.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with epilepsy aged 6 to 12 years. Exclusion criteria: Taking folate supplements or other therapies such as vitamins or antioxidants within the last 3 months, unwillingness to cooperate, metabolic diseases, chronic medical conditions including anemia and gastrointestinal disease associated with malabsorption, neuropsychological diseases and neurodegenerative disorders

Intervention groups

Intervention: Patients will be assigned into two groups to receive folate (n=27) or placebo (n=27). Folate and placebo tablets are similar in shape and size.

Main outcome variables

Outcomes: Carotid intima-media thickness (primary outcome) and biomarkers of inflammation and oxidative stress (secondary outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201704225623N110**

Registration date: **2017-05-09, 1396/02/19**

Registration timing: **retrospective**

Last update: **2019-09-23, 1398/07/01**

Update count: **1**

Registration date

2017-05-09, 1396/02/19

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 36 1534 3570

Email address

asemi_z@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date

2015-03-17, 1393/12/26

Expected recruitment end date

2015-07-17, 1394/04/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of folate supplementation compared with the placebo on carotid intima-media thickness and metabolic profiles in patients with epilepsy

Public title

Effect of supplementation in treatment of patients with epilepsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Aged 2 to 12 years Patients with epilepsy Receiving carbamazepine monotherapy

Exclusion criteria:

Taking folate supplements or other therapies such as vitamins or antioxidants within the last 3 months
Unwillingness to cooperate Metabolic diseases Chronic medical conditions including anemia and gastrointestinal disease associated with malabsorption
Neuropsychological diseases, and neurodegenerative disorders

Age

From **2 years** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done by the use of computer-generated random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, investigators or the assessors of the outcomes are unaware of the study groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8814187159

Approval date

2015-03-16, 1393/12/25

Ethics committee reference number

6011

Health conditions studied

1

Description of health condition studied

Epilepsy

ICD-10 code

G40

ICD-10 code description

Episodic and paroxysmal disorders

Primary outcomes

1

Description

Carotid intima-media thickness

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Sonography

Secondary outcomes

1

Description

Nitric oxide

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

2

Description

Malondialdehyde

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

3

Description

Hs-CRP

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa kit

4

Description

Total antioxidant

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

Intervention groups

1

Description

Intervention group: Folate supplements (Tehran darou, Tehran, Iran), 5000 mg, daily, for 12 weeks orally.

Category

Treatment - Drugs

2

Description

Control group: Placebo tablet, daily for 12 weeks orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Naghavi Clinic

Full name of responsible person

Zatollah Asemi

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Shahid Rajaei Avenue, Kashan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kashan University of

Medical Sciences

Full name of responsible person

Gholamali Hamidi

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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

Vice chancellor for research, Kashan University of Medical Sciences

Proportion provided by this source

100

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

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

PhD of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

PhD of Nutrition

Latest degree

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