Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 placebos 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
Isfehan
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
Street address
Shahid Rajaee Avenue, Kashan
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1771844351
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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
Street address
Ghotbe Ravandi Boulevard, Kashan
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hamidi_gh@kaums.ac.ir
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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Person responsible for updating data

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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