

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Effect of Folate Supplementations and their Relationship with Methyl Tetra Hydrofolate Reductase Folic Acid Polymorphisms on Metabolic, Inflammatory Indices and Nerve Conduction Velocity Variations in Patients with Diabetic Polyneuropathy

Protocol summary

Study aim

Effect of Folate Supplementations and their Relationship with Methyl Tetra Hydrofolate Reductase Folic Acid Polymorphisms on Metabolic, Inflammatory Indices and Nerve Conduction Velocity Variations in Patients with Diabetic Polyneuropathy

Design

In this research, 80 eligible patients with diabetic polyneuropathy were chosen and a code was allocated to each one of them. Then, patients were randomly divided into two control and intervention groups.

Settings and conduct

The present study is a triple-blind randomized clinical trial study and participants, researcher, and statistical analyser will not know from assigned intervention. The population includes patients with diabetic neuropathy referring to Ilmum Musasadr Clinic in Isfahan. The number of participants will include 80 patients and the subjects will be divided into two groups. Patients in the intervention and control group will receive 1 mg per day folic acid or placebo for two months. After diagnosis of diabetic neuropathy by neurologist will examine the polymorphisms of MTHFR gene including C677T and A1298C. At the first and end study plasma folic acid, metabolic indices, C-reactive protein inflammatory marker and nerve conduction velocity variations will be examined.

Participants/Inclusion and exclusion criteria

Patients with diabetic polyneuropathy, >20 years old, diabetic neuropathy approved by the neurologist by the EMG-NCV, the desire to participate in the study, the desire to consume folic acid within 8 weeks; non-diabetic neuropathic patients, pregnant or planning pregnant women, alcohol users, smoking, multivitamin-containing minerals containing folic acid, B12 and B6 consumers during the study, drugs such as methotrexate,

bacterium, antiepileptic and sulfa antibiotics

Intervention groups

The patients with diabetic polyneuropathy in the treatment group will receive folic acid supplements for 8-weeks and patients in the other group also will receive the placebo tablets.

Main outcome variables

Metabolic, inflammatory and nerve conduction velocity variations

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121216011763N22**

Registration date: **2018-01-08, 1396/10/18**

Registration timing: **retrospective**

Last update: **2018-01-08, 1396/10/18**

Update count: **0**

Registration date

2018-01-08, 1396/10/18

Registrant information

Name

Gholamreza Askari

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1792 2110

Email address

askari@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan university of medical sciences

Expected recruitment start date

2016-03-19, 1394/12/29

Expected recruitment end date

2017-11-21, 1396/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Folate Supplementations and their Relationship with Methyl Tetra Hydrofolate Reductase Folic Acid Polymorphisms on Metabolic, Inflammatory Indices and Nerve Conduction Velocity Variations in Patients with Diabetic Polyneuropathy

Public title

Effect of Folic Acid Supplementation among Diabetic Polyneuropathy Patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

>20 Years Old Diabetic Neuropathy Approved by the Neurologist Desire to Consume Folic Acid during 8 Weeks

Exclusion criteria:

Non-Diabetic Neuropathic Patients Pregnant Women Alcohol Users Smoking Multivitamin-minerals Containing Folic Acid, B12 and B6 Consumers during Study Drugs Consumers that may Interfere with the Absorption Folic Acid such as methotrexate, bacterium, antiepileptic and sulfa antibiotics

Age

From **20 years** old to **80 years** old

Gender

Both

Phase

0

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In present study, simple randomization method will be used. The randomization unit is individually and we will use the random number table method for random sequences. A random numbered table is a collection of numbers that are without a specific pattern, completely random and as table. The next step is allocation

concealment and will use sequentially numbered, sealed, opaque envelopes. Then, based on the sample size, number of envelopes with aluminum surface are provided and each random sequence created on a card and the cards are inserted into the envelopes, respectively. At the time of registration for the participants, according to eligible participants, one of the envelopes is opened and the allocated group for participants is revealed.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The present study is a triple blind method and participants, researcher, and statistical analyser will not know according to assigned intervention.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Isfahan university of Medical Sciences

Street address

Hezar Jirib Street, Isfahan, Isfahan University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2017-03-10, 1395/12/20

Ethics committee reference number

IR.MUI.REC.1395.2.285

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

Diabetic Polyneuropathy

ICD-10 code

E11.42

ICD-10 code description

Type 2 diabetes mellitus with diabetic polyneuropathy

Primary outcomes

1

Description

Nerve Conduction Velocity

Timepoint

week 0 and week 8

Method of measurement

EMG-NCV

2

Description

serum folic acid

Timepoint

week 0 and week 8

Method of measurement

Laboratory analysis (blood test)

3

Description

serum vitamin B12

Timepoint

week 0 and week 8

Method of measurement

Laboratory analysis (blood test)

4

Description

Serum homocystein

Timepoint

week 0 and week 8

Method of measurement

Laboratory analysis (blood test)

Secondary outcomes

1

Description

CRP

Timepoint

Week 0 and week 8

Method of measurement

Laboratory analysis (blood test)

2

Description

HbA1C

Timepoint

Week 0 and week 8

Method of measurement

Laboratory analysis (blood test)

Intervention groups

1

Description

Intervention group: Folic acid supplement, tablet 1 mg/day, 8- weeks, Maad pharmacy company

Category

Treatment - Drugs

2

Description

Control group:placebo, 1 mg/day, 8- weeks, School of Pharmacy Isfahan university of medical sciences.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Mousa Sadr Clinic

Full name of responsible person

Tayebeh Mottaghi

Street address

Shohada Square, Foroughi Ave, Imum Mousa Sadr Clinic

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3792 3171

Email

askari@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Isfahan University of Medical Sciences

Full name of responsible person

Amir mansour alavi

Street address

Hezar Jarib Ave, Isfahan University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3792 3171

Email

am.alavi@nutr.mui.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, Isfahan 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**

Isfahan University of Medical Sciences

Full name of responsible person

Tayebeh Mottaghi

Position

PhD Student of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Hezarjarib Street, Isfahan University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3792 3171

Fax**Email**

tmottaghi@yahoo.com

Web page address

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3792 3171

Fax**Email**

askari@mui.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Tayebeh Mottgahi

Position

PhD Student of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Hezarjirib Strreet, Isfahan University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3792 3171

Fax**Email**

tmottaghi@yahoo.com

Web page address**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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Dr Gholamreza Askari

Position

PhD of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Hezarjarib street, Isfahan University of Medical Sciences

City

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