Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Clinical trial Comparison of the Effect of Folic Acid and Vitamin D Supplementation in the Prevention of Cerebrovascular Attacks in Patients Referred to Shahid Beheshti Hospital in 3 Months

Protocol summary

Study aim
In this clinical trial, we plan to evaluate the effect of folic acid and vitamin D supplements on the progression of stroke intensity based on the NIHSS questionnaire over 3 months in patients referred to Shahid Beheshti Hospital between 1969 and 98.

Design
Clinical trial, with parallel, triple, randomized group

Settings and conduct
This study will be conducted trivially, so that the patient, the therapist, the person who evaluates the outcome and the statistician who is responsible for analyzing the data, will be unaware of the type of medication. The random allocation method is based on blocking. Four blocks are used. The list of 24 blocks is written and randomly a number is selected and the sampling is continued based on it.

Participants/Inclusion and exclusion criteria
Individual consent; Hemorrhagic or ischemic stroke with any severity; Age between 30 and 60; Do not take nutritional supplements such as vitamins; no pregnancy; Not having a history of allergy to drugs; The first episode of Stroke; Having no problem swallowing; a resident of Qom province

Intervention groups
Control group A: Stroke patients undergoing routine treatment. Along with the placenta two other drugs Group B: A stroke group that is treated with oral administration of oral folic acid for three months at a dose of 5 mg once a day. Along with vitamin D placebo Group C: A group of patients with a stroke who is given a prescription for vitamin D in addition to routine treatment for three months at a dose of 1000 IU once a day. With Folic Acid Placebo Group D: A group of patients suffering from stroke, administered in addition to routine treatment, administered folic acid for three months at a dose of 5 mg once a day and a prescriptive vitamin D administered at a dose of 1000 IU once a day.

Main outcome variables
The occurrence of stroke types again

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190305042937N1**
Registration date: **2019-08-10, 1398/05/19**
Registration timing: **registered_while_recruiting**

Last update: **2019-08-10, 1398/05/19**
Update count: **0**

Registration date
2019-08-10, 1398/05/19

Registrant information

Name
soroush sharifimoghadam

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 7789 6429

Email address
soroush9566@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-23, 1398/05/01

Expected recruitment end date
2020-03-20, 1399/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Clinical trial Comparison of the Effect of Folic Acid and Vitamin D Supplementation in the Prevention of Cerebrovascular Attacks in Patients Referred to Shahid Beheshti Hospital in 3 Months

Public title
effect of folic acid and vitamin D in stroke
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
No previous use of supplements No pregnancy Ability to swallow medicine Not having a history of allergy Individual consent First episode of stroke
Exclusion criteria:
Pregnancy Not ability to swallow medicine
Age
From **30 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
The random allocation method is based on blocking. Four blocks are used. The list of 24 blocks is written and randomly a number is selected and the sampling is continued based on it ABCD, ABDC, ACBD, ACDB, ADBC, ADCB, BACD, BADC, BCAD, BCDA, BDAC, BDCA, CABD, CADB, CBAD, CBDA, CDAB, CDBA, DABC, DACB, DBCA, DBAC, DCAB, DCBA
Blinding (investigator's opinion)
Triple blinded
Blinding description
Medications and placebo are packed in one form. The packages are written in abbreviated form A, B, C and D and delivered to the secretary. It should be noted that the secretary does not know the content of the packages. According to the patient's entry into the plan, depending on the outcome of the patient's blockage, the packet will be delivered and detailed descriptions of how the medications will be given by the clerk.
Placebo
Used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Qom University of Medical Sciences
Street address
Research Deputy, Safashahr Ave, Mohammadamin Ave
City
Qom
Province
Ghoum
Postal code
3713649373
Approval date
2018-12-04, 1397/09/13
Ethics committee reference number
IR.MUQ.REC

Health conditions studied

1

Description of health condition studied
Brain stroke
ICD-10 code
G90-G99
ICD-10 code description
Other disorders of the nervous system

Primary outcomes

1

Description
Occurrence of recurrent stroke
Timepoint
once a month
Method of measurement
NIHSS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Group B: A stroke group that is treated with oral administration of oral folic acid for a period of three months at a dose of 5 mg once a day. Along with vitamin D placebo
Category

Treatment - Drugs

2

Description
Intervention group: Group C: A group of patients with a stroke who is given a prescription for vitamin D in addition to routine treatment for a period of three months at a dose of 1000 IU once a day. With Folic Acid Placebo
Category
Treatment - Drugs

3

Description
Intervention group: Group D: A group of patients suffering from stroke, administered in addition to routine treatment, administered folic acid for a period of three months at a dose of 5 mg once a day and a prescriptive vitamin D administered at a dose of 1000 IU once a day.
Category
Treatment - Drugs

4

Description
Control group: Control group A: Stroke patients undergoing routine treatment. Along with the placenta two other drugs
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Beheshti hospital
Full name of responsible person
Soroush sharifimoghadam
Street address
Shahid beheshti hospital - Qom
City
Qom
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Ghoum
Postal code
3713649373
Phone
+98 25 3612 2000
Email
bmc@muq.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Dr Ehsan Sharifipur
Street address
Qom university of medical sciences, Lavasani Ave, Qom
City
Qom
Province
Ghoum
Postal code
36122000
Phone
+98 25 3770 6470
Email
bmc@muq.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ghoum 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
Ghoum University of Medical Sciences
Full name of responsible person
Ehsan Sharifipur
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Neurology
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Ehsan sharifipur

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Neurology

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Person responsible for updating data

Contact

Name of organization / entity
Ghoum University of Medical Sciences

Full name of responsible person
Soroush Sharifimoghadam

Position
Medical intern

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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Beheshti hospital, Qom

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Part of the information is shared after deleting the name of the identifier

When the data will become available and for how long
Start access after article release

To whom data/document is available
Only for researchers

Under which criteria data/document could be used
Just use to have background for future studies

From where data/document is obtainable
Neuroscience Research Center of Shahid Beheshti Hospital

What processes are involved for a request to access data/document
Email to the Head of Neurology Department of Qom University of Medical Sciences

Comments