Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of Ellagic acid on depression, inflammatory index (IFN-γ), oxidative (Nrf2) and nitrosative (NO) stress index, Brain Derived Neurotrophic Factor (BDNF), cortisol, serotonin and gene expression of indoleamine dioxygenase enzyme in patients with multiple sclerosis

Protocol summary

Study aim

The aim of this study is to evaluate the effect of Ellagic acid in patients with multiple sclerosis.

Design

12-week randomized, double blinded, parallel clinical trial on 46 patients with multiple sclerosis.

Settings and conduct

Patients are randomly assigned to block randomization in two groups of placebo and supplement. Intervention group received two 90 mg ellagic acid capsules, and the placebo group received two placebo capsules (containing cellulose) in the same color, shape, and odor as the ellagic acid supplement daily for 12 weeks before lunch and dinner. Research process is described for each patient and a written consent form is obtained from all the patients. The 3-day of 24-hour dietary recall is taken at the beginning and end of the study. Patients compliance is monitored by telephone every two weeks. Fasting blood samples are taken from patients at the beginning and end of study. The study protocol has been approved by the ethics committee of Iran University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Willingness 18 -55 years Depression according to Beck's questionnaire (score above 10) No change in the dose of antidepressant medication in the last three months Patients are at recurrence and recovery EDSS <5.5

Intervention groups

The intervention group received two 90 mg ellagic acid capsules, and the placebo group received two placebo capsules (containing cellulose) in same color, shape, and odor as the ellagic acid supplement daily for 12 weeks before lunch and dinner.

Main outcome variables

Depression Score (Beck Questionnaire); Serum level of IFN-γ; Nrf2; NO; BDNF; Cortisol; Serotonin and IDO gene expression and Extensive Disability Severity Score (EDSS)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091114002709N54**
Registration date: **2020-06-07, 1399/03/18**
Registration timing: **prospective**

Last update: **2020-06-07, 1399/03/18**
Update count: **0**

Registration date

2020-06-07, 1399/03/18

Registrant information

Name

Farzad Shidfar

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8862 2755

Email address

shidfar.f@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-05, 1399/05/15

Expected recruitment end date

2021-11-06, 1400/08/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Ellagic acid on depression, inflammatory index (IFN-γ), oxidative (Nrf2) and nitrosative (NO) stress index, Brain Derived Neurotrophic Factor (BDNF), cortisol, serotonin and gene expression of indoleamine dioxygenase enzyme in patients with multiple sclerosis

Public title
Ellagic acid in multiple sclerosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to cooperate Age range 18 to 55 years Depression according to Beck's questionnaire (score above 10) No change in the dose of antidepressant medication in the last three months Diagnosis of MS by a neurologist Patients are at recurrence and recovery EDSS <5.5
Exclusion criteria:
Take nutritional, antioxidant, and ellagic acid supplements for a month before the study (except for routine supplements, which are part of the treatment plan for all patients, such as vitamin D) Pregnancy and lactation Drug abuse History of diabetes and other chronic diseases History of other autoimmune diseases Occurrence of recurrence of the disease during study Taking corticosteroids, estrogens, progesterone, immunosuppressants, diuretics during last month Dose changes and the type of medication used during study Change in physical activity Acceptance rate of less than 90% of supplementation Lack of willingness to cooperate
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **46**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization method has been used for randomization. Blocks size of 4 are generated using www.sealedenvelope.com. In order to conceal the randomization process, individual codes have been on the medicine boxes, which are produced by the software.
Blinding (investigator's opinion)
Double blinded
Blinding description
In order to apply concealment in the randomization process, individual codes will be used on the medicine boxes and the desired code will also be produced by the software.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2020-06-01, 1399/03/12
Ethics committee reference number
IR.IUMS.REC.1399.280

Health conditions studied

1

Description of health condition studied
Multiple sclerosis
ICD-10 code
G35
ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
IFN-γ
Timepoint
At the beginning and end of the intervention
Method of measurement
Laboratory kit

Secondary outcomes

1

Description
Depression score
Timepoint
The beginning and the end of the intervention
Method of measurement
Beck questionnaire

2

Description
Nrf2
Timepoint
The beginning and end of the intervention
Method of measurement
Laboratory kit

3

Description
NO
Timepoint
The beginning and end of the intervention
Method of measurement
Laboratory kit

4

Description
BDNF
Timepoint
The beginning and the end of the intervention
Method of measurement
Laboratory kit

5

Description
Cortisol
Timepoint
The beginning and the end of the intervention
Method of measurement
Laboratory kit

6

Description
Serotonin
Timepoint
The beginning and the end of the intervention
Method of measurement
Laboratory kit

7

Description
IDO gene expression
Timepoint
The beginning and end of the intervention
Method of measurement
Real Time RT-PCR

8

Description
EDSS
Timepoint
The beginning and the end of the intervention
Method of measurement
EDSS QUESTIONNAIRE

Intervention groups

1

Description
Intervention group: The intervention group receives two 90 mg allagic acid capsules daily for 12 weeks before lunch and dinner.
Category
Treatment - Other

2

Description
Control group: The placebo group takes two placebo capsules (containing cellulose) in the same color, shape, and odor as the ellagic acid supplement daily for 12 weeks before lunch and dinner.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasul Akram Hospital
Full name of responsible person
Farzad Shidfar
Street address
Department of Nutrition, School of Public Health, Iran University of Medical Sciences, Shahid Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 86701
Email
farzadshidfar@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person

Dr. Seyyed Abbas Motevallian

Street address
Iran University of Medical Sciences, Shahid Hemmat Highway

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 8670 2504

Email
research-m@iums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Farzad Shidfar

Position
Full Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
Iran University of Medical Sciences, Shahid Hemmat Highway

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 86701

Email
shidfar.f@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Farzad Shidfar

Position
Full Professor

Latest degree
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Street address
Iran University of Medical Sciences, Shahid Hemmat Highway

City
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Province
Tehran

Postal code
1449614535

Phone
+98 21 86701

Email
farzadshidfar@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Farzad Shidfar

Position
Full Professor

Latest degree
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Other areas of specialty/work
Nutrition

Street address
Iran University of Medical Sciences, Shahid Hemmat Highway

City
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Province
Tehran

Postal code
1449614535

Phone
+98 21 86701

Email
farzadshidfar@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information.

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

Information on the main outcomes at the end of the study can be shared

When the data will become available and for how long

The access period will be 6 months after the publication of the results.

To whom data/document is available

The data from the study will only be available to researchers working at academic and scientific institutions.

Under which criteria data/document could be used

6 months after the publication of the papers of this project, upon request from the corresponding author and his agreement, the data can be made available to researchers.

From where data/document is obtainable

Applicants can contact the corresponding author by email or the following postal address to receive the required data. Nutrition department, School of health, Iran University of Medical Sciences, Hemmat highway, Tehran. Email: farzadshidfar@yahoo.com

What processes are involved for a request to access data/document

applicants will be able to access the data from the present study no later than one week by sending an email to the corresponding author.

Comments