

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The effect of Oleoylethanolamide (OEA) supplementation on oxidative stress parameters in multiple sclerosis patients : A randomized clinical trial

Protocol summary

Study aim

Evaluation of the effect of oleoyl ethanamide supplementation on inflammatory parameters and biomarkers of oxidative stress in MS patients

Design

A total of 50 patients were randomly divided into two groups receiving oleoyl ethanamide supplement and placebo by simple random sampling method. Clinical trial with control group, with parallel groups, three-way blind, randomized

Settings and conduct

Fifty patients referred to Shahid Beheshti Hospital in Hamadan (consecutively) who have MS at the diagnosis of a physician, were randomly divided into two groups with respect to allocation (Allocation Concealment). Blinding all organs so that patients are known only by computer code. The treatment codes will be revealed at the end of the study, and it is unclear whether a placebo or supplement will be given, as the placebo capsules will look exactly like oleoyl ethanamide. Written consent is obtained from patients to participate in the study and participate in sampling. After the intervention, blood is taken from these patients and examined.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness to cooperate Recurrent-restricted MS patient Exclusion conditions: Immunosuppressive drugs History of rheumatic and collagen and vascular diseases History of recent infections (during the last 2 to 3 months) Swallowing disorders who are unable to take drugs Sensitivity To non-regular use compounds complement the unwillingness to cooperate

Intervention groups

The intervention group should receive 2 oleoyl ethanamide supplements (250 mg) daily with main meals for 6 weeks. The control group should also take 2 placebo capsules daily for 6 weeks.

Main outcome variables

Inflammatory parameters and biomarkers of oxidative stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210419051012N1**

Registration date: **2021-07-08, 1400/04/17**

Registration timing: **prospective**

Last update: **2021-07-08, 1400/04/17**

Update count: **0**

Registration date

2021-07-08, 1400/04/17

Registrant information

Name

Amirhassan Karimjafari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0000

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-05, 1400/05/14

Expected recruitment end date

2021-11-05, 1400/08/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Oleoylethanolamide (OEA) supplementation on oxidative stress parameters in multiple sclerosis patients : A randomized clinical trial

Public title

The effect of Oleoylethanolamide supplementation on oxidative stress parameters in multiple sclerosis patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

MS type of relapsing_remitting MS patients are treating with beta interferon Willingness to cooperate Patients with an age range of 20 to 40 years

Exclusion criteria:

MS patients are treating with Corticosteroids Taking immunosuppressive drugs History of rheumatic and collagen and vascular diseases History of recent infections (during the last 2 to 3 months) Swallowing disorders that are unable to take medication Sensitivity to compounds No regular use of supplements Reluctance to cooperate

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

More than 1 sample in each individual

Number of samples in each individual: **2**

Before eating supplement and after that

Randomization (investigator's opinion)

Randomized

Randomization description

For this purpose, we will use the method of four random blocks (Block Randomization). For this purpose, we prepare four sheets of paper. Write the letter A on two sheets and the letter B on the other two sheets. (Only researcher knows code A, B is an intervention or placebo). The mixed sheets are placed in the pharmacy desk drawer. Upon referral to any of the eligible patients, one of the leaflets is randomly pulled out and based on this leaflet is A or B. The desired drug is removed from box A or B and delivered to the patient. And the type of medicine received is recorded. It should be noted that the extracted sheets will not be returned to the drawer until all four sheets have been removed. After randomly

pulling out all four sheets, all the sheets are returned to the drawer and the above procedure will be continued for the next four patients until the desired sample size (50 patients) is reached.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study is a three-blind study in which the patient, physician and analyst have no information about the type of drug used. In this way, after explaining the study to Binar and obtaining written permission from him, the doctor instructed the patient to refer to the pharmacy to receive DA or placebo. Do not mix with the pharmacist delivered with the code a, b and make it available to the pharmacy. The pharmacy provides the patient with the drugs identified by the code a, b randomly blocking the patient. Also, when evaluating the results, the analyst will be informed about the type of drug in the two groups with the code a and b, and after completing the analysis, this coding will be determined by the researcher.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethics Committee of Hamadan University of Medical Sciences

Street address

Shahid Fahmideh Blvd., Hamadan University of Medical Sciences

City

Hamedan

Province

Hamadan

Postal code

6517838678

Approval date

2021-01-19, 1399/10/30

Ethics committee reference number

IR.UMSHA.REC.1399.874

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

red blood cell

Timepoint

Before and after the intervention

Method of measurement

laboratory

2

Description

white blood cell

Timepoint

Before and after the intervention

Method of measurement

laboratory

3

Description

plt

Timepoint

Before and after the intervention

Method of measurement

laboratory

4

Description

Interleukin 17

Timepoint

Before and after the intervention

Method of measurement

ELISA

5

Description

TNF- α

Timepoint

Before and after the intervention

Method of measurement

ELISA

6

Description

UREA

Timepoint

Before and after the intervention

Method of measurement

Labratory

7

Description

TG

Timepoint

Before and after the intervention

Method of measurement

Laboratory

8

Description

Cholesterol

Timepoint

Before and after the intervention

Method of measurement

Laboratory

9

Description

PLT

Timepoint

Before and after the intervention

Method of measurement

Laboratory

10

Description

Total antioxidant capacity

Timepoint

Before and after the intervention

Method of measurement

Spectrophotometer

11

Description

Catalase enzyme activity

Timepoint

Before and after the intervention

Method of measurement

Spectrophotometer

12

Description

Protein oxidation

Timepoint

Before and after the intervention

Method of measurement

Spectrophotometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Take two oleoyl ethanamide supplements (250 mg) daily orally for six weeks. Supplements are provided by Karen Company.

Category

Treatment - Drugs

2

Description

Control group: Take two placebo capsules daily (capsule that is not oleoyl ethanlamide but patients have not been told about it) for 6 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamadan Shahid Beheshti Hospital

Full name of responsible person

Amir Ghiasian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Akram Ranjbar

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Toxicology

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

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Phone**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

Not applicable

Data Dictionary

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