Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 ethanlamide. 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
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Iran (Islamic Republic of)
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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 suplement 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
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Sponsors / Funding sources

1

Sponsor
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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
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Other areas of specialty/work
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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
Not applicable

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