Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of Oleoyl ethanolamide (OEA) supplementation on blood hematological parameters, lipid profile, biomarkers of oxidative stress and inflammatory parameters in the blood of patients with acute ischemic brain stroke

Protocol summary

Study aim
Effect of Oleoyl ethanolamide supplementation on hematologic parameters, lipid profile, inflammatory parameters and oxidative stress biomarkers in patients with acute ischemic stroke

Design
40 patients Individually were divided into two groups by the simple randomization method and by the decimal number table and receiving Oleoyl ethanolamide supplementation. Clinical trial with control group, With parallel groups, Three blind strains, Accidental

Settings and conduct
40 patients referred to Sina Hospital of Hamadan (consecutively) diagnosed with a physician with acute ischemic stroke were randomly divided into two groups with Allocation Concealment. Blinding of all organs as patients know only by computer code. Therapeutic codes are revealed at the end of the study and it is unclear whether the placebo or supplement is taken because the placebo capsules will be made to look very similar to Oleoyl ethanolamide. . Patients receive written consent to participate in the study and to participate in the sampling. After intervention, blood sample is taken and examined.

Participants/Inclusion and exclusion criteria
Entry requirements: Willingness to cooperate Acute ischemic stroke Exclusion criteria: taking immunosuppressive drugs History of rheumatic and collagen and vascular diseases History of recent infections (within 2 to 3 months) Swallowing disorders that are unable to take medication Sensitivity to compounds No regular use of supplements Not willing to cooperate Diabetes kidney disease

Intervention groups
The intervention group received a daily supplement of Oleoyl ethanolamide (200 mg) along with main meals for 2 months. The control group should also take a placebo capsule daily for 2 months.

Main outcome variables
Hematologic parameters, lipid profile, inflammatory parameters and oxidative stress biomarkers

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130501013194N4**
Registration date: **2019-12-28, 1398/10/07**
Registration timing: **prospective**

Last update: **2019-12-28, 1398/10/07**
Update count: **0**

Registration date
2019-12-28, 1398/10/07

Registrant information

Name
Akram Ranjbar

Name of organization / entity
Hamedan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 81 1838 0031

Email address
a.ranjbar@umsha.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2020-01-20, 1398/10/30

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Oleoyl ethanolamide (OEA) supplementation on blood hematological parameters, lipid profile, biomarkers of oxidative stress and inflammatory parameters in the blood of patients with acute ischemic brain stroke

Public title

The effect of Oleoyl ethanolamide (OEA) supplementation in patients with acute ischemic brain stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to cooperate Acute ischemic brain stroke (preferably under one month)

Exclusion criteria:

taking immunosuppressive drugs History of rheumatic and collagenvascular diseases History of recent infections (within 2 to 3 months) Swallowing disorders that are unable to take medication Sensitivity to compounds No regular use of supplements Not willing to cooperate Diabetes kidney disease

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

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

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

This is an interventional study with a randomized controlled trial study design. In this study, 40 patients referred to Sina Hospital of Hamadan (consecutively) with diagnosis of acute ischemic stroke physician will be included in the study. In this study, patients were randomly divided into two groups of Oleoyl ethanolamide and placebo with Allocation Concealment by random number table and based on their group of supplements receive the relevant for two months. They will receive a computer code. The personal code of any participant in this course of treatment is not disclosed. Treatment codes are revealed at the end of the study after the database is closed.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participants receive the relevant supplements for two months after obtaining written consent from the group in which they are located. They will receive a computer code. The personal code of any participant in this course of treatment is not disclosed. Treatment codes are revealed at the end of the study after the database is closed. Capsules and placebo are similar in appearance, so clinical caregivers, researchers, outcome assessors and data analysts and the Committee on Safety and Data Monitoring know patients only by code and do not know which patient received the supplement or placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Hamedan University of Medical Sciences

Street address

Fahmedeh Blvd., Hamedan University of Medical Sciences

City

Hamedan

Province

Hamadan

Postal code

6517838678

Approval date

2019-12-06, 1398/09/15

Ethics committee reference number

IR.UMSHA.REC.1398.720

2

Ethics committee

Name of ethics committee

Ethic committee of Hamedan University of Medical Sciences

Street address

Fahmedeh Blvd., Hamedan University of Medical Sciences

City

Hamedan

Province

Hamadan

Postal code
6517838678
Approval date
2019-12-07, 1398/09/16
Ethics committee reference number
IR.UMSHA.REC.1398.721

3

Ethics committee
Name of ethics committee
Ethic committee of Hamedan University of Medical Sciences
Street address
Fahmedeh Blvd., Hamedan University of Medical Sciences
City
Hamedan
Province
Hamadan
Postal code
6517838678
Approval date
2019-12-07, 1398/09/16
Ethics committee reference number
IR.UMSHA.REC.1398.722

Health conditions studied

1

Description of health condition studied
Acute ischemic brain stroke
ICD-10 code
I63.9
ICD-10 code description
Cerebral infarction, unspecified

Primary outcomes

1

Description
Red blood cells
Timepoint
Before and after intervention
Method of measurement
Laboratory

2

Description
White blood cells
Timepoint
Before and after intervention
Method of measurement
Laboratory

3

Description
Platelets
Timepoint
Before and after intervention
Method of measurement
Laboratory

4

Description
Alanine aminotransferase
Timepoint
Before and after intervention
Method of measurement
Laboratory

5

Description
Aspartate aminotransferase
Timepoint
Before and after intervention
Method of measurement
Laboratory

6

Description
Cholesterol
Timepoint
Before and after intervention
Method of measurement
Laboratory

7

Description
Triglyceride
Timepoint
Before and after intervention
Method of measurement
Laboratory

8

Description
High density lipoprotein
Timepoint
Before and after intervention
Method of measurement
Laboratory

9

Description
Low density lipoprotein
Timepoint
Before and after intervention
Method of measurement
Laboratory

10

Description
Urea
Timepoint

Before and after intervention
Method of measurement
Laboratory

11

Description
Creatinine
Timepoint
Before and after intervention
Method of measurement
Laboratory

12

Description
Lipid peroxidation
Timepoint
Before and after intervention
Method of measurement
Using spectrophotometer

13

Description
Protein oxidation
Timepoint
Before and after intervention
Method of measurement
Using spectrophotometer

14

Description
Total antioxidant capacity
Timepoint
Before and after intervention
Method of measurement
Using spectrophotometer

15

Description
Catalase activity
Timepoint
Before and after intervention
Method of measurement
Using spectrophotometer

16

Description
Tumor necrosis factor alpha
Timepoint
Before and after intervention
Method of measurement
ELISA

17

Description
Interleukin 17
Timepoint
Before and after intervention
Method of measurement
ELISA

18

Description
Reactive Protein C
Timepoint
Before and after intervention
Method of measurement
Turbidometry

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: They take one oleoyl ethanolamide supplement (200 mg) daily for two months. Supplements are made by Karen.
Category
Treatment - Drugs

2

Description
Control group: They receive a placebo capsule daily (a capsule that is not Oleoyl ethanolamide but patients are not told) for 2 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Mojtaba Khazaei
Street address
Mirzadeh Eshqi St, Sina Hospital
City
Hamedan
Province
Hamadan
Postal code
6516848741
Phone
+98 81 3827 4191
Email
a.ranjbar@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Saeed Bashirian

Street address
Fahmedeh Blvd., Hamedan university of medical sciences

City
Hamedan

Province
Hamadan

Postal code
6517838678

Phone
+98 81 3525 0182

Email
a.ranjbar@umsha.ac.ir

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

Street address
Fahmedeh Blvd., Hamedan university of medical sciences

City
Hamdan

Province
Hamadan

Postal code
6517838678

Phone
+98 81 3827 4191

Email
a.ranjbar@umsha.ac.ir

Person responsible for scientific 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

Street address
Fahmedeh Blvd., Hamedan university of medical sciences

City
Hamdan

Province
Hamadan

Postal code
6517838678

Phone
+98 81 3827 4191

Email
a.ranjbar@umsha.ac.ir

Person responsible for updating data

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

Street address
Faculty of Pharmacy, Hamadan University of Medical Sciences, Shahid Fahmide Street, Hamadan, Iran

City
Hamadan

Province
Hamadan

Postal code
6517838678

Phone
+98 81 1838 0031

Fax
+98 81 1838 0031

Email
a.ranjbar@umsha.ac.ir

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