Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Survey the effect of resveratrol supplementation on some oxidative stress and inflammatory biomarkers, fatigue scale, fasting blood sugar and lipid profile in patients with Multiple Sclerosis.

Protocol summary

Study aim
Determination the effect of resveratrol supplementation on some oxidative stress and inflammatory biomarkers, fatigue scale, fasting blood sugar and lipid profile in patients with Multiple Sclerosis.

Design
A clinical trial with control group including a sample size of 60 people, with parallel group, double-blind, randomized

Settings and conduct
Referred to the Khouzestan MS Association in 2023, selection of 60 patients based on inclusion and exclusion criteria, randomization into intervention and control groups. Blinding of patients and researchers, coding by a third party who does not know the details.

Participants/Inclusion and exclusion criteria
The disease is diagnosed according to McDonald's criteria. EDSS score 0 to 5 The clinical condition of the patient is relapse-remittance. Age 18 to 65 years The patient consumes alcohol, tobacco or drugs. Use of antioxidant supplements and hormonal treatments. Body mass index(BMI) higher than 30. Any progressive or autoimmune diseases.

Intervention groups
Study groups include resveratrol and placebo consumer groups

Main outcome variables
MDAT, TNF-α, Fasting blood sugar, Lipid profile, Fatigue Scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230315057731N1**
Registration date: **2023-05-12, 1402/02/22**
Registration timing: **registered_while_recruiting**

Last update: **2023-05-12, 1402/02/22**
Update count: **0**

Registration date
2023-05-12, 1402/02/22

Registrant information

Name
Sara Keramatzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 3571 2847

Email address
sarakeramatzadeh@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-21, 1402/02/01

Expected recruitment end date
2023-10-06, 1402/07/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Survey the effect of resveratrol supplementation on some oxidative stress and inflammatory biomarkers, fatigue scale, fasting blood sugar and lipid profile in patients with Multiple Sclerosis.

Public title

Resveratrol in multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The disease is diagnosed according to McDonald's criteria. EDSS score 0 to 5 The clinical condition of the patient is relapse-remittance. Age 18 to 65 years

Exclusion criteria:

The patient consumes alcohol, tobacco or drugs. Use of antioxidant supplements and hormonal treatments. Body mass index(BMI) higher than 30. Any progressive or autoimmune diseases.

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Allocation of patients to each of the study groups will be done using random block method and using blocks of six. The blocks are designed by the statistical consultant and each block contains A or B, which represents the group receiving the drug or placebo. Patients receive the type of treatment (A or B) according to the order of entering the study and in the order specified by the randomization blocks. Unit codes are also applied in both packages containing medicine or placebo in advance, which means, for example, the first person who meets the study entry criteria, if based on the block, should receive medicine A, from the general box containing medicine A, one can It is randomly removed and given to the patient (the two-digit number on the can may be, for example, 15). The use of unit codes is based on the expert opinion of the statistics consultant and is used to prevent the breaking of A and B codes.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the double-blind method will be used to reduce the possibility of information bias. In this way, both the patients and the researchers will be kept unaware of the type of treatment assigned to the subjects. For this purpose, resveratrol and placebo packages will be divided into A and B groups by someone outside the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz. Golestan Bolvar. Jundishapur University of Medical Sciences. Research Assistance

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2023-03-11, 1401/12/20

Ethics committee reference number

IR.AJUMS.REC.1401.588

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

Tumor Necrosis Factor Alpha (TNF-α)

Timepoint

Before and two months after intervention

Method of measurement

ELISA

2

Description

MDA

Timepoint

Before and two months after intervention

Method of measurement

ELISA

3

Description
fatigue scale
Timepoint
Before and two months after intervention
Method of measurement
MFIS questionnaire

Secondary outcomes

1

Description
Fasting Blood Sugar
Timepoint
Before and two months after intervention
Method of measurement
Enzymatic

2

Description
Lipid Profile (TC , TG, HDL, LDL)
Timepoint
Before and two months after intervention
Method of measurement
Enzymatic

Intervention groups

1

Description
Intervention group: 500 mg of resveratrol (in the form of two capsules made by Raha Company) for 8 weeks
Category
Treatment - Drugs

2

Description
Control group: tow placebo per day (made by Raha company) for 8 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Khouzestan MS Association
Full name of responsible person
Mazie Zilaee
Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan street
City
Ahvaz
Province
Khouzestan
Postal code
1579461357
Phone
+98 61 3336 2414
Email
zilaee-m@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Dr Mehrnoosh Zakerkish
Street address
Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences, Golestan street, Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
15794-61357
Phone
+98 61 3336 2414
Email
itc@ajums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Sara Keramatzadeh
Position
M.Sc student of Nutrition Science
Latest degree
Bachelor
Other areas of specialty/work

Nutrition

Street address
Department of Nutrition, School of Allied Medical Sciences, Ahvaz Jundishapur University of Medical Sciences, Golestan St., Ahvaz

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Phone
+98 61 3571 5794

Email
Sarakeramatzadeh@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Marzie Zilaee

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
Department of Nutrition, School of Allied Medical Sciences, Jundishapur University of Medical Sciences, Golestan St., Ahvaz

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Phone
+98 61 3311 2713

Email
zilaee-m@ajums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Sara Keramatzadeh

Position
M.Sc student of Nutrition Science

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

Street address
Department of Nutrition, School of Allied Medical Sciences, Ahvaz Jundishapur University of Medical Sciences, Golestan St., Ahvaz

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Phone
+98 61 3311 2713

Email
Sarakeramatzadeh@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
The person's information will be confidential and the results will be as collective statistics

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

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