

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 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

Registration timing: **registered_while_recruiting**

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.

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

Update count: **0**

Registration date

2023-05-12, 1402/02/22

Design

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

Registrant information

Name

Sara Keramatzadeh

Name of organization / entity

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Iran (Islamic Republic of)

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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.

Recruitment status

Recruitment complete

Funding source

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.

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

Intervention groups

Study groups include resveratrol and placebo consumer groups

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.

Main outcome variables

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

Public title

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230315057731N1**

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

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

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Ahvaz

Province

Khuzestan

Postal code

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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: two placebo per day (made by Raha company) for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Khuzestan MS Association

Full name of responsible person

Mazie Zilae

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Ahvaz Jundishapur University of Medical Sciences,
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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Dr Mehrnoosh Zakerkish

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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

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

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Marzie Zilaei

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Assistant Professor

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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