

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Effects of Oral Caffeine on Fatigue in Multiple Sclerosis Patients: A Randomized Double Blind Clinical Trial

Protocol summary

Study aim

To evaluate the effect of oral caffeine consumption on fatigue levels in patients with multiple sclerosis.

Design

A phase 3, randomized, double-blind, controlled clinical trial conducted on 60 patients.

Settings and conduct

The researchers in this study will collect questionnaire-based and demographic data from patients presenting to Bu-Ali Sina Hospital in Sari during the year 1403 (2024-2025). The placebo tablets, identical in size and color, are prepared at the Faculty of Pharmacy. These tablets will be distributed in identical packaging based on a random number table. Both patients and clinical physicians conducting the study, as well as those involved in data collection and chart review, will remain blinded to the group allocation of the participants, ensuring a double-blind design.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Adult patients aged 18 years and older diagnosed with multiple sclerosis, Obtaining informed consent, Fatigue score (MIFS) > 33. Exclusion Criteria: Diagnosis of depression, Hypothyroidism, Anemia, Hypertension, Cardiac arrhythmias, Caffeine sensitivity, Concurrent use of medications affecting fatigue, Lack of consent to participate or continue in the study, Irregular medication use or non-adherence to the study schedule, History of using medications containing caffeine, Recent caffeine consumption within the past week, Pregnancy.

Intervention groups

The intervention involves administering 100 mg caffeine tablets daily to the intervention group, while the placebo group will receive identical placebo tablets. Before and after the three-month intervention period, patients will complete the fatigue assessment questionnaire and the quality of life questionnaire to evaluate changes in fatigue levels and quality of life.

Main outcome variables

پیامد اولیه مطالعه ارزیابی میزان خستگی و میزان تغییر نمره خستگی بیماران متعاقب دریافت گروه مداخله و یا پلاسیبو می باشد.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241129063892N1**

Registration date: **2024-12-08, 1403/09/18**

Registration timing: **prospective**

Last update: **2024-12-08, 1403/09/18**

Update count: **0**

Registration date

2024-12-08, 1403/09/18

Registrant information

Name

Mohammad Baghbanian

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 911 151 8209

Email address

mohammadbaghbanian@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-12-14, 1403/09/24

Expected recruitment end date

2025-04-20, 1404/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effects of Oral Caffeine on Fatigue in Multiple Sclerosis Patients: A Randomized Double Blind Clinical Trial

Public title

Effect of Oral Caffeine on Fatigue in Multiple Sclerosis Patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Adult patients aged 18 years and older diagnosed with multiple sclerosis Obtaining informed consent. Having a fatigue score (MFIS) greater than 33.

Exclusion criteria:

Diagnosis of depression Anemia Hypothyroidism Hypertension Cardiac arrhythmias Caffeine sensitivity Concurrent use of medications affecting fatigue Lack of consent to participate or continue in the study Irregular medication use or non-adherence to the study schedule History of using medications containing caffeine. Pregnancy Recent caffeine consumption within the past week.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation of patients into the caffeine and placebo groups will be performed using the method of randomized blocks. It should be noted that the block size will be determined completely randomly to ensure the allocation of the last participant in each block. According to the aforementioned protocol, a total of 60 patients (30 in each group) will be enrolled in the study and assessed for the outcomes of caffeine consumption. For example, suppose the first randomly generated block consists of four participants with the following sequence: A for the intervention group and B for the control group: A B B A In this case, the first participant will be assigned to the intervention group, the second and third to the control group, and the fourth to the intervention group. Subsequent blocks will be generated with random sizes, and this process will continue until all 60 patients are allocated to the two groups. It is worth mentioning that the intervention and control groups will be matched for

variables such as age, gender, weight, and height. After matching and determining the blocks, participants will be numbered sequentially upon enrollment. Group allocation within each block will be determined using the Random Allocation Software version 2, and the codes will be placed in numbered envelopes. For each patient, the corresponding envelope will be opened, and the assigned intervention will be implemented.

Blinding (investigator's opinion)

Double blinded

Blinding description

Given the study design, the drug and placebo will be prepared in identical packaging in terms of size and color and will be numbered based on the randomization table. Both the patients and the clinical physicians conducting the study, as well as those involved in data collection and chart review, will remain blinded to the group allocation of the participants. This ensures a double-blind design.

Placebo

Used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Ethics committee of Mazandaran University of Medical Sciences

Street address

Research and Technology Vice-Chancellor's Building, Moallem Square

City

Sari

Province

Mazandaran

Postal code

4815733971

Approval date

2024-10-01, 1403/07/10

Ethics committee reference number

IR.MAZUMS.REC.1403.328

Health conditions studied**1****Description of health condition studied**

Fatigue in multiple sclerosis

ICD-10 code**ICD-10 code description**

Primary outcomes

1

Description

Fatigue score in the Modified Fatigue Impact Scale (MFIS) questionnaire

Timepoint

At the beginning of the study and three months after caffeine consumption.

Method of measurement

Modified Fatigue Impact Scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Administration of 200 mg caffeine tablets (manufactured by Eurho Vital), at a dose of half a tablet (equivalent to 100 mg) once a day, for a duration of three months.

Category

Treatment - Drugs

2

Description

Control group: Administration of placebo tablets, at a dose of half a tablet once a day, for a duration of three months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu-Ali Sina Hospital

Full name of responsible person

Mohammad Baghbanian

Street address

Pasdarán Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Ahmad Ali enayati

Street address

Research and Technology Vice-Chancellor's Building,
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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

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Aida gharanjig

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Demographic information, questionnaire data, and details related to the primary outcome will be shared after anonymizing the individuals.

When the data will become available and for how long

The access period will commence six months after the publication of the results.

To whom data/document is available

Researchers affiliated with academic and scientific institutions will be granted access to the data.

Under which criteria data/document could be used

For scientific and research purposes

From where data/document is obtainable

To obtain the documentation, please send your request to the project manager, Dr. Mohammad Baghbanian, at Mohammadbaghbanian@gmail.com.

What processes are involved for a request to access data/document

After submitting the request, the necessary evaluations will be conducted, and the results will be sent to the applicant's email address.

Comments