Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 پلاسبو 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

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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
Pasdaran Blvd
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Fax
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Booali.sina54@gmail.com

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, Moallem Square
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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
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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