Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Investigation of the effect of cocoa powder on fatigue severity in patients with multiple sclerosis(MS) in comparison with placebo effect

Protocol summary

Study aim
The effect of oral cocoa powder on symptoms of fatigue among patients with multiple sclerosis (MS) compared to placebo

Design
A clinical trial without a control group, triple blinded, randomized

Settings and conduct
The study is a randomized, tripple-blind clinical trial for 2 months in MS patients referred to Kashani hospital neurology. The drug will be taken 25 g daily in the morning and afternoon doses. Patients will take the drug regularly for eight weeks. If you forget a dose of the drug, you can take the drug for an hour later, and if you forget the drug for more than one hour, reapply for the next hour. If the drug is not taken for two consecutive days or forgotten for a total of 10 doses, these patients will be excluded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Consent to participate in the study; MS with Relapsing remitting form; Less than 10 years have passed since their diagnosis; Age between 20 and 50 years; Have a Fatigue severity scale above 4; The EDSS score is below 6; Have a recent anemia and hypothyroid rejection test in one month; Exclusion criteria: Have recurrent in the past 3 months; The disease involves the CNS except migraine; They have acute febrile illness; Have systemic autoimmune disease; Based on Beck Depression Inventory moderate or severe (Questionnaire score above 20); Currently taking neurotoxic drugs including: antipsychotic agents, monoamine oxidase inhibitors, benzodiazepines, tricyclic antidepressant drugs, anticonvulsants, beta blockers and barbiturates

Intervention groups
We have two intervention groups. The first group received the drug in the form of 12.5 grams of cocoa powder, and the second group received a placebo containing 2.5 grams of cocoa powder.

Main outcome variables
Fatigue

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171030037093N34**
Registration date: **2020-03-28, 1399/01/09**
Registration timing: **prospective**

Last update: **2020-03-28, 1399/01/09**
Update count: **0**

Registration date
2020-03-28, 1399/01/09

Registrant information

Name
Sadra Ansaripour

Name of organization / entity
Shahrekord University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 31 3650 3487

Email address
st_ansari.s@skums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-03-30, 1399/01/11

Expected recruitment end date
2020-06-29, 1399/04/09

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigation of the effect of cocoa powder on fatigue severity in patients with multiple sclerosis(MS) in comparison with placebo effect

Public title
The effect of cocoa powder on fatigue in multiple sclerosis patients

Purpose
Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:
Consent to participate in the study MS with Relapsing remitting form Less than 10 years have passed since their diagnosis Age between 20 and 50 years Have a Fatigue severity scale above 4. The EDSS score is below 6 Have a recent anemia and hypothyroid rejection test in one month

Exclusion criteria:
Have recurrent in the past 3 months The disease involves the CNS except migraine They have acute febrile illness Have systemic autoimmune disease Based on Beck Depression Inventory moderate or severe (Questionnaire score above 20) Currently taking neurotoxic drugs including: antipsychotic agents, monoamine oxidase inhibitors, benzodiazepines, tricyclic antidepressant drugs, anticonvulsants, beta blockers and barbiturates

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients in the study were randomly assigned to either A or B groups using computer software.

Blinding (investigator's opinion)
Triple blinded

Blinding description
At first the drug powder and placebo optionally into groups A and B are packed without the knowledge of a physician, patient, or analyzer (note that only the first person knows that package A is the drug or placebo). The software is divided into recipient groups A and recipient B, which will be written in the form A or B.After completing the design and final analysis, the packaging person announces that A B Which powder (drug or placebo) each had. According to this physician, the patient and the analyzer were unaware of the groups until after the data was analyzed

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences

Street address
Isfahn University of Medical Sciences, Hezar Jerib Avenue, Isfahan

City
Isfahan

Province
Isfehan

Postal code
7346181746

Approval date
2019-11-26, 1398/09/05

Ethics committee reference number
IR.MUI.MED.REC.1398.445

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
Fatigue

Timepoint
Before and after the study

Method of measurement
With MFIS and FSS questionnaires

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The drug will be administered in the form of 12.5 grams of cocoa powder after dissolving in a glass of water half an hour before or one hour after meals.
Category
Treatment - Drugs

2

Description
Control group: receive placebo. Each placebo pack contains 2.5 grams of cocoa powder (much less than the effective and therapeutic dose of cocoa) that can be used in 200 cc of boiling water or milk.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kashani hospital
Full name of responsible person
Iman Adibi
Street address
Kashani Street, Isfahan Province, Isfahan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjooy Javanmard
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sh_haghjoo@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Iman Adibi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Full name of responsible person

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Position

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Latest degree

Specialist

Other areas of specialty/work

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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

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