Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of phoenix Dactylifera supplementary on fatigue in patients with multiple sclerosis

Protocol summary

Study aim
Determining the effect of phoenix Dactylifera supplement on fatigue in patients with multiple sclerosis

Design
A clinical trial with a control group, double-blind, randomized phase 3 clinical trial on 50 patients.

Settings and conduct
The research community will consist of multiple sclerosis patients referred to the clinics of Arak University of Medical Sciences. Patients will be divided into two control and intervention groups based on the randomized method. Patients of both groups will complete demographic and fatigue severity questionnaire before the start of the study. Patients in the control group received phoenix Dactylifera supplement capsules and the intervention group received placebo capsules containing starch powder .Six weeks after the start of the intervention, the fatigue severity questionnaire will be completed by two groups.

Participants/Inclusion and exclusion criteria
Having a history of multiple sclerosis for at least 3 months, having an age range of 18 to 60 years, not being pregnant, not having food and drug allergies (Date products), obtaining a score of 28 or more on the Fatigue Severity Scale (FSS), Not taking anti-depressants and anti-fatigue drugs.

Intervention groups
The intervention group in this study will receive 84 capsules of 300 mg of phoenix Dactylifera supplement and they will be told to consume them twice a day at 10:00 PM and 10:00 AM for 42 days. Similarly, the control group will be given 84 placebo capsules and they will be asked to take them twice a day at 10 pm and 10 am for 42 days.

Main outcome variables
fatigue severity questionnaire

General information

Reason for update

Acronym
Multiple sclerosis (MS)

IRCT registration information
IRCT registration number: **IRCT20230706058689N1**
Registration date: **2023-12-29, 1402/10/08**
Registration timing: **prospective**

Last update: **2023-12-29, 1402/10/08**
Update count: **0**

Registration date
2023-12-29, 1402/10/08

Registrant information

Name
Farnoosh Ansari

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-30, 1402/10/09

Expected recruitment end date
2024-03-09, 1402/12/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of phoenix Dactylifera supplementary on fatigue in patients with multiple sclerosis

Public title
The effect of phoenix Dactylifera supplementary on fatigue in patients with multiple sclerosis

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Having a history of MS for at least 3 months (based on the information in the patient's file) Age 18 to 60 years Absence of food and drug allergy (date products) Obtaining a score of 28 or more in severe measurement (FSS) Obtaining informed consent Absence of pregnancy (pregnancy during the study period or decision to become pregnant at the beginning of the study)

Exclusion criteria:
The use of antidepressants The use of other medications effective in relieving fatigue (Ritalin, Pemoline, Amantadine)

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

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

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization method will be used in this study. Also, the unit of randomization is individual, and patients with multiple sclerosis who meet the study entry criteria based on their willingness to participate in the research, were included in the study non-randomly and then randomly by block randomization method (block of four) in two groups A. and B are assigned. In this study, due to having the volume of four blocks, six different states will be imagined for the blocks, which are: AABB, ABAB, ABBA, BBAA, BABA, BAAB. Different states of blocks will be written on cardboard cards of the same size and color. According to the sample size (50 patients) and six types of blocks, the number of cards 9 times randomly by re-replacing the selection and order of blocks will determine the order of placement of patients in groups A (control) and B (intervention).

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, doctors, patients, and statistical analysts are not aware of the allocation of patients in the intervention and control groups. In this study, patients in the test group will only receive capsules containing starch, and patients in the control group will also receive capsules containing starch. Starch will be offered to patients in the exact same packaging and color as phoenix Dactylifera capsules due to its similarity in appearance with phoenix Dactylifera. Similarly, in order to make the statistical analyst unaware, the control and intervention groups are marked with code one and two, so that only the researcher knows about the control and intervention groups. The doctor introduces the patients to the researcher, and due to the fact that the drug under study is not among the essential drugs for the patients and does not require a doctor's prescription, the doctor does not know about the allocation of patients in the control and intervention groups.

Placebo
Used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committees of Arak University of Medical Sciences

Street address
Management of Research and Medical Information, Deputy of Research and Technology, University Complex of the Prophet (pbuh), Basij Square

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Markazi

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3819693345

Approval date
2023-10-28, 1402/08/06

Ethics committee reference number
IR.ARAKMU.REC.1402.178

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 score based on the Fatigue Severity Scale (FSS)
Timepoint
Measuring the severity of fatigue at the beginning (before the start of the intervention) and 6 weeks after the start of the intervention
Method of measurement
Fatigue severity scale Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: phoenix dactylifera (Date Palm pollen), 300 mg capsules, twice a day at 10 am and 10 pm, place of production: Tehran Faculty of Pharmacy, Medical Sciences
Category
Treatment - Other

2

Description
Control group: placebo (containing starch), 300 mg capsules, twice a day at 10 am and 10 pm, place of production: Tehran Faculty of Pharmacy, Medical Sciences
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Hospital Vali-Asr
Full name of responsible person
Farnoosh Ansari Asl
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Arak 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
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Full name of responsible person
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Person responsible for updating data

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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