

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3511

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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

City

Arak

Province

Markazi

Postal code

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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Vali-Asr St, Vali-Asr Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mehdi Salehi

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Deputy of Research and Technology, University complex of the great prophet (pbuh), Basij Square, Sardasht

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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

Arak University of Medical Sciences

Full name of responsible person

Ali Jadidi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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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