

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Clinical Trial of the Effect of Traditional Medicine Product (majoon baadam) on Multiple Sclerosis-related Fatigue level

Protocol summary

Summary

This research aims to achieve an effective inexpensive traditional medicine treatment for MS-related fatigue by study on the effect of a traditional medicine-based product (Majoon Baadam) to reduce MS-related fatigue. The key inclusion criteria are: MS diagnosis based on McDonald criteria by a neurologist adviser, MS-related fatigue lasting at least one month, consciously accepting subscription form, no simultaneous anti-fatigue medical treatment, Expanded Disability Status Scale (EDSS) equal or less than 6, MFIS more than 45, no crisis of disease over the previous 60 days. Key exclusion criteria are: relapse of disease over the study period, uncontrolled diabetes, blood hypertension, pregnant or lactating mothers, severe infection and severe mental disorders. Seventy MS patients after fulfillment of inclusion and exclusion criteria, randomly use either product or placebo with certain daily dose for four weeks (35 patients in each group). Product and placebo are given by director of pharmacy to the patients in similar coded packs and coded forms will be processed by researcher, so in this way blinding of patients and researcher is done(double-blind). On this basis all patients will be checked before and 4 weeks after intervention by primary outcome measures including Modified Fatigue Impact Scale (MFIS), Visual Analog Scale (VAS) and secondary outcome measures including PITTSBURGH SLEEP QUALITY INDEX (PSQI), Rome III criteria for constipation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014050317545N1**

Registration date: **2014-05-24, 1393/03/03**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-05-24, 1393/03/03

Registrant information

Name

Mehdi Sardari

Name of organization / entity

Tehran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Faculty of Traditional Iranian Medicine of Tehran University of Medical Sciences

Expected recruitment start date

2014-05-25, 1393/03/04

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical Trial of the Effect of Traditional Medicine Product (majoon baadam) on Multiple Sclerosis-related Fatigue level

Public title

Effect of Traditional Medicine Product on MS-related Fatigue

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: MS diagnosis, either relapsing remitting (RR) secondary progressive (SP) or primary progressive, based on specified criteria of modern medicine by MC.Donald criterion approved with neurologist; MS-related fatigue lasting at least one month and there should be indication of anti fatigue treatment; consciously accepting subscription form/ letter of satisfaction; patient shouldn't be under simultaneous anti-fatigue medical treatment; not using any other natural or herbal treatment by the patient during the study; lack of any record of sensitivity to drug ingredients; EDSS equal or less than 6; MFIS more than 45; no crisis of disease over the previous 60 days and Exclusion criteria: relapse of disease over the study period; uncontrolled diabetes; blood hypertension; pregnant or lactating mothers; severe infection; severe mental disorders

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

501, 5th Floor, Central Building of Tums, Keshavarz and Qods Junction, Tehran, Iran

City

Tehran

Postal code

Approval date

2013-10-09, 1392/07/17

Ethics committee reference number

130/1485/92/3

Health conditions studied

1

Description of health condition studied

Neurasthenia, Malaise and fatigue

ICD-10 code

F48, R53

ICD-10 code description

Neurasthenia, Malaise and fatigue

2

Description of health condition studied

Multiple Sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description

Modified Fatigue Impact Scale (MFIS) Standard Questionnaire

Timepoint

Before intervention and after four weeks

Method of measurement

Filling out Modified Fatigue Impact Scale (MFIS) Standard Questionnaire by the patient

2

Description

Visual Analog Scale (VAS) for Fatigue

Timepoint

Before intervention and after four weeks

Method of measurement

Filling out Visual Analog Scale (VAS) by the patient

Secondary outcomes

1

Description

Sleep Quality of patients contributed in the study

Timepoint

Before intervention and after four weeks

Method of measurement

Filling out Pittsburgh Sleep Quality Index (PSQI) by the patient

2

Description

Constipation in patient

Timepoint

Before intervention and after four weeks
Method of measurement
Filling out Rome III Criteria for constipation module by the patient

Intervention groups

1

Description

In intervention group: Using product (majoone badaam) with 15 grams daily dose, orally, divided into three times: fasting, one hour before lunch, one and half to two hrs after lunch over four weeks.

Category

Treatment - Drugs

2

Description

In control group: Using placebo with 15 grams daily dose, orally, divided into three times: fasting, one hour before lunch, one and half to two hrs after lunch over four weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Traditional Iranian Medicine of TUMS

Full name of responsible person

Mehdi Sardari

Street address

Corner of Behesht St, Hasanabad Square, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Faculty of Traditional Iranian Medicine of Tehran University of Medi

Full name of responsible person

Dr.Mohammad bagher Minaee

Street address

Corner of Behesht St, Hasan Abad Square

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Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research of Faculty of Traditional

Iranian Medicine of Tehran University of Medi
Proportion provided by this source
100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Bagher Minae

Position

Deputy director of research of Faculty of Traditional Iranian Medicine of TUMS

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty