Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of Femi Locket on the fatigue of multiple sclerosis patients referring to the clinics of Arak University of Medical Sciences

Protocol summary

Study aim
Investigating the effect of Famillact on the fatigue of multiple sclerosis patients

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 30 patients.

Settings and conduct
This study is a double-blind study on multiple sclerosis patients who have been suffering from this disease for at least 6 months. In this way, after obtaining permission from the university's research council, patients referred to the clinics of Arak University of Medical Sciences are examined based on clinical examinations by neurologists and paraclinical results to confirm the diagnosis of multiple sclerosis. The patients were randomly divided into two experimental and control groups, the experimental group was also prescribed Famillact 500 mg per day in addition to the standard drugs. Homogeneous in the control group, in addition to standard drugs, a placebo drug is also given. At zero time and after 30 and 60 days of drug administration, the patients were assessed for fatigue caused by multiple sclerosis using the standard "Fatigue Severity Scale" (FSS) checklist.

Participants/Inclusion and exclusion criteria
Having a history of multiple sclerosis for 6 months Neurological examination and brain CT scan and ruling out brain tumors and space-occupying lesions Absence of mental illnesses including depression and absence of psychiatric problems and nervous headaches Absence of accompanying diseases that cause fatigue, including thyroid diseases and anemia - Exit criteria: Reluctance to continue studying Presence of sensitivity to Famillact

Intervention groups
Famillact group

Main outcome variables
Fatigue

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240609062052N3**
Registration date: **2024-08-11, 1403/05/21**
Registration timing: **registered_while_recruiting**

Last update: **2024-08-11, 1403/05/21**
Update count: **0**

Registration date
2024-08-11, 1403/05/21

Registrant information

Name
Pouya Zeidy

Name of organization / entity
Khomein University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 86 4633 2435

Email address
zeidypouya@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-07-13, 1403/04/23

Expected recruitment end date
2024-09-22, 1403/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of Femi Locket on the fatigue of multiple sclerosis patients referring to the clinics of Arak University of Medical Sciences

Public title
Investigating the effect of Femi Locket on the fatigue of multiple sclerosis patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having a history of multiple sclerosis for 6 months Neurological examination and brain CT scan and ruling out brain tumors and space-occupying lesions Absence of mental illnesses including depression and absence of psychiatric problems and nervous headaches Absence of accompanying diseases that cause fatigue, including thyroid diseases and anemia

Exclusion criteria:
Presence of sensitivity to Femilact

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
The names of all patients will be written completely randomly from top to bottom after sampling the required amount (30 people) using the available (easy) sampling method; Then, from the top, we assign number 1 to the first person, then 2 to... the last person to whom we assign the number 30. Then numbers 1 to 15 will be assigned to the control group and numbers 16 to 30 to the intervention group.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, only the patients and the project manager who is supposed to perform the intervention on the patients; They will be blind. In this way, the empty capsule will be prepared exactly the same as the Familact capsule, and 30 glasses will be prepared for the drugs. According to the randomization, glasses 1 to 15 will contain 3 empty capsules each and glasses number 16 to 30 will contain 3 Familact capsules each. In this way, both the project manager and the patient will not know whether the capsule they receive is Familact or a placebo.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Khomein Faculty of Medical Sciences

Street address
Quds Avenue

City
Khomein

Province
Markazi

Postal code
3881743364

Approval date
2024-05-28, 1403/03/08

Ethics committee reference number
IR.KHOMEIN.REC.1403.004

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 the start of the intervention, 30 and 60 days after the start of the intervention

Method of measurement
"Fatigue Severity Scale" (FSS) standard checklist

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Placebo Group

Category

Placebo

2

Description
Intervention group: Familact Group
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Valieasr Hospital
Full name of responsible person
Mahdi Safarabadi
Street address
Hazrat Valieasr square
City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 2222 0038
Email
pr_valieasr@arakmu.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khomein Faculty of Medical Sciences
Full name of responsible person
Abbas Farahani
Street address
Quds Avenue
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3881743364
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info@khomeinums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Khomein Faculty 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
Khomein Faculty of Medical Sciences
Full name of responsible person
Mahdi Safarabadi
Position
Professor Assistant
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Position
Professor Assistant

Latest degree
Ph.D.

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Nursery

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3881743364

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+98 86 4622 4142

Email
mahdisafarabadi@gmail.com

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
All information and data will be shared after de-identifying people.

When the data will become available and for how long
Access will start 1 month after the results are published.

To whom data/document is available
All people related to medical and health matters

Under which criteria data/document could be used
The use of data will only be subject to mention of the source of the study and the authors. It is definitely necessary to obtain permission from the authors and researchers of the study.

From where data/document is obtainable
With this E-Mail:Mahdisafarabadi@gmail.com

What processes are involved for a request to access data/document
After submitting the request and explaining the reason for the request, Dr. Safarabadi, the scientific accountability officer, will review the request and finally, within 72 hours after the request, the result will be informed to the requester.

Comments