Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation Of Effectiveness Of The Lavander Flower (Lavandula angustifolia Mill) On Fatigue In Multiple Sclerosis Patients - Double-Blind Clinical Trial

Protocol summary

Study aim
Determination of the Effect of Lavender on the Mean Score of MFIS (Modified Fatigue Impact Scale) Questionnaire in Patients with Multiple Sclerosis Compared to Placebo

Design
This study is a double-blind clinical trial. 60 patients are randomly divided into intervention and placebo groups (30 patient in each group)

Settings and conduct
This study is performed on patients with MS who are registered in the Kerman Neurology Research Center. Based on the inclusion and exclusion criteria, 60 patients are selected and entered into the study after completing the consent form.Patients are randomly assigned to one of two groups (intervention and placebo). The researcher and patients are not aware of the contents of the drug packages.

Participants/Inclusion and exclusion criteria
Main inclusion criteria: Definitive diagnosis of MS according to McDonald's criteria and confirmed by a neurologist; Relapsing-remitting type of MS; Having symptoms of fatigue; Expanded Disability Status Score (EDSS) of less than or equal to 6; No disease attack during the last month; Not using other medication during study. Exclusion criteria: Disease attack during the study; The emergence of drug complications; Not willingness to continue the study; Pregnancy; Breastfeeding.

Intervention groups
Intervention group:receiving 500 mg capsule (600 mg lavender) every 8 hours and placebo group: receiving 500 mg capsule (corn starch) every 8 hours

Main outcome variables
Fatigue in patients with multiple sclerosis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190710044166N1**
Registration date: **2019-09-03, 1398/06/12**
Registration timing: **prospective**

Last update: **2019-09-03, 1398/06/12**
Update count: **0**

Registration date
2019-09-03, 1398/06/12

Registrant information

Name
Najmeh Motaghi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 34 3248 1040

Email address
n.motaghi@kmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-06, 1398/06/15

Expected recruitment end date
2020-02-04, 1398/11/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation Of Effectiveness Of The Lavander Flower (Lavandula angustifolia Mill) On Fatigue In Multiple Sclerosis Patients - Double-Blind Clinical Trial

Public title
Efficacy of lavender in the treatment of fatigue in patients with multiple sclerosis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Definitive diagnosis of MS according to McDonald's criteria and confirmed by a neurologist Relapsing-remitting type of MS Having symptoms of fatigue Expanded Disability Status Score (EDSS) of less than or equal to 6 No disease attack during the last month Not using other medication during the study No Depression disease Based on Beck Questionnaire No history of other diseases such as autoimmune disease, malignancy No usind of drugs such as antipsychotic , monoamine oxidase inhibitors, benzodiazepines, tricyclic antidepressants, anticonvulsants and barbiturates

Exclusion criteria:
Disease attack during the study The emergence of drug complications Not willingness to continue the study Pregnancy Breastfeeding

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

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

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Block Randomization(4 block) In this study, there are two groups A and B (Medicine and placebo). In the 4 blocks, there are 6 groups of positions A and B (AABB, ABAB, BAAB, BABA, BBAA, ABBA). By using the random number table, the order of these 6 states is determined. Finally, the entry of groups A and B are determined according to the 6 states and the random number table.

Blinding (investigator's opinion)
Double blinded

Blinding description
The drug packages are packaged and coded by the pharmacist and the researcher and patient are unaware of it.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Research Vice-Chancellor, Ebn Sina Avenue

City
Kerman

Province
Kerman

Postal code
7619837773

Approval date
2019-08-25, 1398/06/03

Ethics committee reference number
IR.KMU.REC.1398.253

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 on the MFIS questionnaire

Timepoint
At baseline and two months after drug administration

Method of measurement
MFIS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Recipient of 3 capsules 500 mg (containing 600 mg lavender) every 8 hours for 2 months

Category
Treatment - Drugs

2

Description
Control group: Recipient of 3 capsules 500 mg (containing corn starch) every 8 hours for 2 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Neurology Research Center
Full name of responsible person
Najmeh Motaghi
Street address
Neurology Research Center, Alley 22, Shafa Avenue
City
Kerman
Province
Kerman
Postal code
7618759639
Phone
+98 34 3212 4727
Email
kmu.nrc@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Dr. Vahid Sheibani
Street address
Neuroscience Research Center, Ebn Sina Avenue
City
Kerman
Province
Kerman
Postal code
7619813159
Phone
+98 34 3226 4196
Email
info.knrc@kmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Najmeh Motaghi
Position
Ph.D Student of Persian Medicine
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
Street address
College of Traditional Iranian Medicine, Amir Kabir Crossroads, Jomhori Blvd.
City
Kerman
Province
Kerman
Postal code
7618843883
Phone
+98 34 3211 0123
Email
n.motaghi34@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Najmeh Motaghi
Position
Ph.D Student of Persian Medicine
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
Street address
College of Traditional Iranian Medicine, Amir Kabir Crossroads, Jomhori Blvd.
City
Kerman
Province
Kerman
Postal code
761883883
Phone
+98 34 3211 0123
Email
n.motaghi34@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Najmeh Motaghi

Position
Ph.D student of pershian Medicine

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

Street address
College of Traditional Iranian Medicine, Amir Kabir Crossroads, Jomhori Blvd.

City
Kerman

Province
Kerman

Postal code
761884883

Phone
+98 34 3211 0123

Email
n.motaghi34@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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

Title and more details about the data/document
After completing the study, the information on the main outcome will be shared.

When the data will become available and for how long
6 months after printing results

To whom data/document is available
Researchers and other people can access data if they need it.

Under which criteria data/document could be used
The data and results can be used for review article, reprogramming and modeling in other studies after printing results.

From where data/document is obtainable
Email: n.motaghi34@yahoo.com

What processes are involved for a request to access data/document
The email will be answered after one week

Comments