Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of hydroalcoholic extracts of Flaxseed (seed of Linum usitatissimum) and Nigella Sativa plants on fatigue in MS patients

Protocol summary

Study aim
Determining the effect of hydroalcoholic extracts of Flaxseed and Nigella Sativa plants on fatigue in MS patients

Design
A double-blind randomized clinical trial with two groups: Flaxseed, Nigella Sativa, and placebo

Settings and conduct
The study will be conducted at Imam Reza Hospital. Patients will be randomly divided into two groups of Flaxseed, Nigella Sativa, and placebo by block method. The study is a double-blind (researchers and participants will not be aware of the groups involved).

Participants/Inclusion and exclusion criteria
Having stable condition for at least 8 weeks before entering the study, The score and assessment of fatigue of the people included in the study by the tests should be higher than the minimum standards, The psychotropic treatment regimens that the patients had before the start of the study should be adjusted for at least 4 weeks before the start of the study, The patient has not had a relapse attack in the last 4 months, The patient has not had an active infection in the last 4 months, The patient has not received a corticosteroid pulse in the last 4 months, History of suicide attempts or suicidal thoughts

Intervention groups
The Flaxseed and Nigella Sativa group will receive a soft gel containing 0.75 ml of each plant every 12 hours for three months. The control group will receive a 1.5 ml soft gel containing additives.

Main outcome variables
The level of fatigue that using the questionnaire before starting the drug and three months later (after taking the drug completely)

General information

Reason for update
The English names of plants are written incorrectly.

Acronym

IRCT registration information
IRCT registration number: **IRCT20140617018126N6**
Registration date: **2022-11-01, 1401/08/10**
Registration timing: **retrospective**

Last update: **2024-11-02, 1403/08/12**
Update count: **1**

Registration date
2022-11-01, 1401/08/10

Registrant information

Name
Mostafa Araj-Khodaei

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
2021-11-22, 1400/09/01

Expected recruitment end date
2022-03-19, 1400/12/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of hydroalcoholic extracts of Flaxseed (seed of Linum usitatissimum) and Nigella Sativa plants on fatigue in MS patients

Public title
The effect of Flaxseed and Nigella Sativa on MS
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with MS who had a stable condition for at least 8 weeks before entering the study The score and assessment of fatigue of the people included in the study by the tests should be higher than the minimum standards The psychotropic treatment regimens that the patients had before the start of the study should be adjusted for at least 4 weeks before the start of the study.
Exclusion criteria:
The patient has not had a relapse attack in the last 4 months The patient has not had an active infection in the last 4 months The patient has not received a corticosteroid pulse in the last 4 months. History of suicide attempts or suicidal thoughts
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Samples will be randomly assigned to six blocks using Random Allocation Software. Blocking and allocation sequences for concealment will be done by the non-involved researcher (Allocation Concealment). The sample allocation ratio will be Allocation 1:1 and will be divided into two groups of receiving Flaxseed and Nigella Sativa, and Placebo. Then based on blocks and allocation sequences, each client will be given white pockets that are prepared in equal sizes and on which the numbers 1 to 50 are written (in order of allocation sequence). The pockets will contain white boxes containing Flaxseed, Nigella Sativa, or Placebo soft gels. Only the person in charge of packing drugs will know the numbers of the relevant pockets and none of the researchers or patients will know the type of medicine each person receives. The first person will be given pocket number 1, which will continue until completion. soft gels will be similar in shape, size, color, and, smell.
Blinding (investigator's opinion)
Double blinded
Blinding description
Based on blocks and allocation sequences each client will be given white pockets that are prepared in equal sizes and on which the numbers 1 to 50 are written (in order of allocation sequence). The pockets will contain white boxes containing Flaxseed and Nigella Sativa, or Placebo capsules. Only the person in charge of packing soft gels will know the numbers of the relevant pockets and none of the researchers or patients will know the type of medicine each person receives. The first person will be given pocket number 1, which will continue until completion. All soft gels will be similar in shape, size, color, and smell.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Research Vice Chancellor, Third Floor, Central Building No. 2, Tabriz University of Medical Sciences, Golgasht Street, Tabriz
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Tabriz
Province
East Azarbaijan
Postal code
5166614766
Approval date
2022-10-10, 1401/07/18
Ethics committee reference number
IR.TBZMED.REC.1401.657

Health conditions studied

1

Description of health condition studied
Fatigue of MS patients
ICD-10 code
G35
ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
Fatigue in MS patients
Timepoint
MFIS questionnaire before taking and three months after taking drugs
Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This group will receive a capsule containing 0.75 ml Flaxseed and 0.75 ml Nigella Sativa soft gels every 12 hours and for 3 months. The capsules will be provided by Sina Noandish Tabiat Company.
Category
Treatment - Drugs

2

Description
Control group: This group will receive a softgel containing 1.5 ml of additives every 12 hours and for 3 months. The capsules will be provided by Sina Noandish Tabiat.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam reza hospital
Full name of responsible person
Seyed Mostafa Araj khodaie
Street address
Imam Reza Hospital, Opposite the Central Organization of the Tabriz University of Medical Sciences, Golgasht Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
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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
Tabriz 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)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available