

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Country

Iran (Islamic Republic of)

Phone

+98 41 3337 9528

Email address

araj@tbzmed.ac.ir

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

City

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

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41 3334 2178

Email

aria@tbzmed.ac.i

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahbi

Street address

Third Floor, Central Building No. 2, Tabriz University
of Medical Sciences, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3335 7310

Email

research-vice@tbzmed.ac.ir

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

Tabriz University of Medical Sciences

Full name of responsible person

Mostafa Araj-Khodaie

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

Aging Research Institute, Faculty of medicine, Tabriz
University of Medical Sciences, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3334 2178

Email

araj@tbzmed.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mostafa Araj-Khodaei

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

Aging Research Institute, Faculty of medicine, Tabriz
University of Medical Sciences, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3334 2178

Email

araj@tbzmed.ac.ir

Other areas of specialty/work

Traditional Medicine

Street address

Aging Research Institute, Faculty of medicine, Tabriz
University of Medical Sciences, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3334 2178

Email

araj@tbzmed.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Mostafa Araj-Khodaei

Position

Assistant Professor

Latest degree

Ph.D.

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