Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effectiveness of soft gel Nigella Sativa on tremor in patients with multiple sclerosis referred to the MS association of khuzestan province

Protocol summary

Study aim

Determination of the effectiveness of soft capsule Nigella Sativa on tremor in patients with MS

Design

A randomized clinical trial with a control group with parallel, double-blind, phase 3 on 32 patients.

Settings and conduct

The research environment is the Musculoskeletal Rehabilitation Research Center located in the Faculty of Rehabilitation, Ahvaz Jundishapur University. At the beginning of the visit (time zero), the researcher will get the patient's history and examination to determine EDSS. in addition patient will complete a quality of life questionnaire and qualitative and quantitative measurement of tremor. Next, the case group will use Nigella sativa 500 mg soft capsule every 12 hours for 6 weeks. The control group will use a placebo soft capsule every 12 hours for 6 weeks. It should be noted that patients are visited at intervals of zero, 6 weeks from the start of treatment, and tremors will be measured and recorded by the motion analysis system.

Participants/Inclusion and exclusion criteria

Inclusion criteria: having proven MS by clinical examination and medical history, confirmation of tremor based on neurologist approval based on clinical criteria, having regular drug treatment in 3 months. Exclusion criteria: pregnancy, lactation, impaired renal or hepatic function, steroid therapy during the month prior to the study.

Intervention groups

In this study, the effect of soft black seed capsules on tremors in MS patients in the study group will be investigated. Placebo will be prescribed in the control group.

Main outcome variables

Tremor amplitude, tremor frequency, quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211206053308N1**
Registration date: **2022-03-19, 1400/12/28**
Registration timing: **registered_while_recruiting**

Last update: **2022-03-19, 1400/12/28**
Update count: **0**

Registration date

2022-03-19, 1400/12/28

Registrant information

Name

Zahra Beigi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3001

Email address

zahrabeygi90@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of soft gel Nigella Sativa on tremor in patients with multiple sclerosis referred to the MS association of khuzestan province

Public title
Effect of Nigella Sativa on tremor
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having a proven MS condition based on clinical examination and medical history Confirmation of tremor based on neurologist approval based on clinical criteria Having an EDSS score between 2 and 6 Having fixed and regular consumption of medication in the last 3 months Consent to not use alternative drugs from 7 days before the intervention until the end of the intervention No attending to another study at the same time
Exclusion criteria:
History of alcohol use or substance abuse Pregnancy or breastfeeding Impaired renal or hepatic function Steroid treatment during the month before the start of the study Having a neurological disease in addition to MS Heart disease or bleeding disorders Existence of allergy to Nigella Sativa The onset of the disease in the last month
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **32**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization will be used in this study. The randomization list will be placed in closed envelopes by an out-of-study person according to the corresponding codes; it is then will be assigned to each patient who will enter the study.The distribution of patients will be done in a ratio of 1: 1 and by 8 blocks (the length of each block is 4), (sample size of this study is 32).The randomization sequence will be created using the randomization command in Excel (randbetween).
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, two groups, including participants and the researcher, are kept blind. To do this, the interventions used in this study were randomized according to the list; Placed in closed envelopes by an out-of-study person according to the corresponding codes; It is then assigned to each patient who enters the study. All patients will continue their treatment regimen as before. Also, two drugs, black seed soft capsule and placebo soft capsule, are prepared in the same package, so that they do not differ in appearance.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz University of Medical Sciences
Street address
West Shahrivar, Ahvaz Town
City
Ahvaz
Province
Khouzestan
Postal code
6135945431
Approval date
2021-12-01, 1400/09/10
Ethics committee reference number
IR.AJUMS.REC.1400.509

Health conditions studied

1

Description of health condition studied
Multiple sclerosis
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Tremor Amplitude
Timepoint
Tremor amplitude measurement at the beginning of the study and six weeks after taking soft capsule Nigella Sativa
Method of measurement
Video motion recording system

2

Description
Tremor frequency
Timepoint
Tremor frequency measurement at the beginning of the study and six weeks after taking soft capsule Nigella Sativa
Method of measurement

Video motion recording system

Secondary outcomes

1

Description
Quality of life
Timepoint
At the beginning of the study and six weeks after taking soft capsule Nigella Sativa
Method of measurement
Questionnaire quality of life

2

Description
Frequency of drug side effects
Timepoint
At the beginning of the study and six weeks after taking soft capsule Nigella Sativa
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: Use soft capsule Nigella sativa 500 mg, Parnian Darman Company, every 12 hours for 6 weeks.
Category
Treatment - Drugs

2

Description
Control group: Use the placebo soft capsule every 12 hours for 6 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
MS association of Khuzestan province
Full name of responsible person
zahra beigi
Street address
West Shahrivar, Ahvaz Town
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
zahra beigi
Street address
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City
Ahvaz
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Khouzestan
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Email
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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
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
zahra beigi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Neurology
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Person responsible for updating data

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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 data can potentially be shared after unidentified individuals.
When the data will become available and for how long
Start of access period from 1402
To whom data/document is available
Study data is available to anyone who applies for it.
Under which criteria data/document could be used
Study data are available to researchers in similar or related studies
From where data/document is obtainable
Nastaran Majdi Nasab, e-mail: n.majdi@ajums.ac.ir Leila Kooti, e-mail: kouti-l@ajums.ac.ir Mohammad Mehravar, e-mail: mehravar-m@ajums.ac.ir Zahra Beigi, Email: zahrabeygi90@gmail.com
What processes are involved for a request to access data/document
The initial written request should be sent with a complete and clear explanation to determine the purpose of using the data, which will be made available to the applicant after reviewing the request for unidentifiable personal data.
Comments