

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

The effect of ginseng in fatigue related to neuromyelitis optica spectrum disorder: a double-blind randomized clinical trial

Protocol summary

Study aim

evaluating the effect of ginseng on fatigue of patients with neuromyelitis optica in comparison with placebo group

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 58 patients. Excel software rand function was used for randomization.

Settings and conduct

In this study, which is designed as a double-blind randomized clinical trial, all definite cases of neuromyelitis optica are examined based on the 2015 diagnostic criteria that refer to the neuromyelitis optica clinic of Sina Hospital from 2019 to 2020, and After obtaining the written consent of the study participants, patients are randomly assigned to the intervention and placebo groups. Patients 'fatigue at the time of enrollment will be calculated according to the Fatigue Severity Scale criteria and patients' disability at the time of enrollment will be calculated according to the Expanded disability status scale criterion.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 2015 diagnostic criteria of neuromyelitis optica exclusion criteria: pregnancy, Concomitant use of anti-fatigue medications, Having concomitant diseases that can affect fatigue

Intervention groups

In the intervention group, patients will receive ginseng with a dose of 250 mg twice a day for 3 months. In the control group, placebo with the same appearance as ginseng will be given twice a day for 3 months. Medication and placebo are made by "Gol Daroo" company.

Main outcome variables

severity of fatigue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200713048095N1**

Registration date: **2020-08-07, 1399/05/17**

Registration timing: **retrospective**

Last update: **2020-08-07, 1399/05/17**

Update count: **0**

Registration date

2020-08-07, 1399/05/17

Registrant information

Name

Abdorreza Naser Moghadasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6634 8572

Email address

moghaddasi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2020-03-20, 1399/01/01

Actual recruitment start date

2019-08-23, 1398/06/01

Actual recruitment end date

2020-01-21, 1398/11/01

Trial completion date

2020-05-21, 1399/03/01

Scientific title

The effect of ginseng in fatigue related to neuromyelitis optica spectrum disorder: a double-blind randomized clinical trial

Public title

The effect of ginseng on fatigue in neuromyelitis optica spectrum disorder

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

2015 diagnostic criteria for neuromyelitis optica spectrum disorder

Exclusion criteria:

pregnancy Concomitant use of anti-fatigue medications
Having concomitant diseases effecting fatigue

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **58**

Actual sample size reached: **58**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomize patients with inclusion criteria Block balanced randomization is used. Before studying, one of the person who is not a member of the research team performs the randomization process using Random generator software, and forms blocks of four for the intervention and control group. The complete cards of the blocks are given to a nurse, who is unaware of the study, in an envelope. A card is given to the patient after patient entrance to the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

The required number of drugs will be provided to the researcher in the research center (equal number of boxes containing the drug and the box containing the placebo), which are not distinguishable in appearance and can only be separated by special codes on the labels affixed to the drug box. Each code will belong to one patient from the beginning to the end of the study, which can be traced with the same code throughout the study period in the patient's research center. The drugs are coded by one person and then the coded drugs are sent to the centers. The person delivering the medicine to the patient does not know what the code was for the medicine or placebo. In this way, the researcher and the patient do not know whether the prescription pills are a drug 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 Tehran University of Medical Sciences

Street address

Central building of Tehran University of Medical sciences, Ghods st, Keshavarz blv.

City

Tehran

Province

Tehran

Postal code

66524185424

Approval date

2020-03-09, 1398/12/19

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.969

Health conditions studied**1****Description of health condition studied**

fatigue in Neuromyelitis optica spectrum disorder (NMOSD)

ICD-10 code

G36.0

ICD-10 code description

Neuromyelitis optica [Devic]

Primary outcomes**1****Description**

Severity of fatigue in Fatigue Severity Scale questionnaire

Timepoint

evaluation of fatigue before intervention and 90 days after administering ginseng or placebo

Method of measurement

Fatigue Severity Scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: will receive Ginseng 250-mg oral tablets twice a day for 3 months. medication is made by "Gol Daroo" company.

Category

Treatment - Drugs

2

Description

Control group: will receive placebo resembling ginseng oral tablets twice a day for 3 months. medication is made by "Gol Daroo" company.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Abdorrezza Naser Moghadasi

Street address

Sina hospital, Imam khomeini st

City

Tehran

Province

Tehran

Postal code

۱۱۳۶۷۴۹۹۸۶

Phone

+98 21 6634 8500

Email

moghaddasi@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraeian

Street address

Central building of Tehran University of Medical sciences, Ghods st, Keshavarz blv.

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3685

Email

vcr@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Abdorrezza Naser Moghadasi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

Street address

Sina Hospital, Hassan abad Sq., Imam Khomeini Ave.

City

Tehran

Province

Tehran

Postal code

1136749986

Phone

+98 21 6634 8572

Fax

Email

moghaddasi@sina.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

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Fax
Email
moghaddasi@sina.tums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Abdorreza Naser Moghadasi
Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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