

# 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

Abdorrezza 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

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#### Postal code

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#### 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

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1417653761

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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.

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

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#### Latest degree

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## Person responsible for updating data

**Contact**  
**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Abdorreza Naser Moghadasi  
**Position**  
Assistant Professor  
**Latest degree**  
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**Other areas of specialty/work**  
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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