

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Clinical trial comparing the efficacy and safety of N-acetylcysteine and amantadine on fatigue and disability and quality of life of patients with MS

#### Protocol summary

##### Study aim

Comparison of the efficacy and safety of N-acetylcysteine and amantadine on fatigue, disability and quality of life of patients with MS referred to Khuzestan MS Association

##### Design

The clinical trial is performed in 112 patients with two groups of parallel, double-blind, randomized, phase 3. To randomize people with the help of software based on the method of 6 random block permutations are completely randomly divided into 2 groups.

##### Settings and conduct

Ahwaz MS Society

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with a definite diagnosis of multiple sclerosis (MS) aged 18 to 50 years who have been at least one month since their last attack of the disease and their degree of disability(EDSS) is between 1 to 5.5 and their fatigue rate according to the Fatigue Severity Scale is 4 Or higher. Conditions of non-entry: taking supplements or drugs with antioxidant properties such as vitamins E and C, zinc, melatonin; Taking medications that cause fatigue and drowsiness (such as benzodiazepines, tricyclic antidepressants, sedatives, anticonvulsants); Taking drugs with stimulants (stimulants), amantadine, dopaminergic; Pregnancy and lactation; Allergy to N-acetylcysteine (NAC); Existence of depression (according to Beck questionnaire); Accompanying medical conditions that can cause fatigue, such as: sleep disorders, heart failure, anemia, hypothyroidism and ....

##### Intervention groups

All patients will continue their treatment regimen as before, and the first group will be treated with NAC (Exir Company) pills at a dose of 600 mg every 12 hours. While for the second group, Amantadine capsules of Ammorel brand (Amin company) will be prescribed at a

dose of 100 mg every 12 hours. The duration of treatment will be 6 weeks

##### Main outcome variables

Fatigue; Expanded Disability Status Scale; Quality of Life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201216049736N1**

Registration date: **2020-12-31, 1399/10/11**

Registration timing: **prospective**

Last update: **2020-12-31, 1399/10/11**

Update count: **0**

##### Registration date

2020-12-31, 1399/10/11

##### Registrant information

##### Name

FATEMEH Ghasemi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3374 3012

##### Email address

fatemeh.ghasemi2280@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-01-04, 1399/10/15

##### Expected recruitment end date

2021-02-03, 1399/11/15

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Clinical trial comparing the efficacy and safety of N-acetylcysteine and amantadine on fatigue and disability and quality of life of patients with MS

**Public title**  
An effectiveness and safety comparison study of N-acetylcysteine and amantadine on fatigue and Disability and quality of life of multiple sclerotic patients

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Patients with definitive diagnosis of MS aged 18 to 50 years Be in the offensive phase (at least one month after the attack) Disability rate according to EDSS criteria is between 1 to 5.5. Fatigue is 4 or higher according to the FSS criteria. If interferon is used to treat multiple sclerosis, at least 6 months have passed since the start of this drug.  
**Exclusion criteria:**  
History of corticosteroid use during the month before treatment Taking supplements or drugs with antioxidant properties such as vitamins E and C, zinc, melatonin Taking medications that cause fatigue and drowsiness (such as benzodiazepines, tricyclic antidepressants, sedatives, anticonvulsants) Taking stimulant drugs, amantadine, dopaminergic drugs Pregnancy and lactation History of NAC allergy or any side effects Existence of depression (according to Beck questionnaire) Accompanying medical conditions that can cause fatigue, such as: sleep disorders, heart failure, anemia, hypothyroidism and ....

**Age**  
From **18 years** old to **50 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **112**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Subjects were randomly divided into two groups based on the method of four random blocks. The site at sealedenvelope.com was used for randomization. If we call the two groups A and B, the logic of randomization is that out of 6 blocks, BBAA, ABBA, ABAB, AABB, BAAB and BABA, we select as many samples by placement (ie as n

/ 4) to Consider the sample size.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
N-acetylcysteine and amantadine are packaged in such a way that the patient does not know the name of the drug he is taking. In the case of amantadine, a darkly labeled drug pack prepared by a non-research nurse removes the amantadine capsules from the original package and places them in these sachets (20 capsules per pack). In the case of N-acetylcysteine, this drug will be produced in the same factory packaging due to its sensitivity to water, but with a concealment label so that the name of the drug is not known. These drugs will be provided to patients by a nurse unrelated to the research, so that the physician responsible for the registration and final analysis of the plan will not be aware of the drug provided to each patient.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**  
All patients will continue their treatment regimen as before and also the first group will be treated with N-acetylcysteine tablets (Exir Company) at a dose of 600 mg every 12 hours. While for the second group, Amantadine capsules of Ammorel brand (Amin Company) will be prescribed at a dose of 100 mg every 12 hours. The duration of treatment will be 6 weeks. Patients' adherence to drug treatment will be reviewed by telephone and during one call per week by the physician in charge of the project, and during this call, possible symptoms and side effects will be questioned. Patients will be visited at the end of the treatment period and EDSS, FSS and MSQOL54 will be calculated for them.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics ComEthics Committee of Ahwaz University of Medical Sciences

##### Street address

Farvardin St., Ahwaz, Golestan Hospital

##### City

Ahwaz

##### Province

Khuzestan

##### Postal code

3311861357

#### Approval date

2020-12-23, 1399/10/03

#### Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1399.128

## Health conditions studied

1

### Description of health condition studied

Multiple sclerosis

### ICD-10 code

G35

### ICD-10 code description

Multiple sclerosis

## Primary outcomes

1

### Description

Fatigue

### Timepoint

Before the intervention and 6 weeks after the intervention

### Method of measurement

Fatigue questionnaire according to Fatigue severity scale

## Secondary outcomes

1

### Description

Degree of disability

### Timepoint

Before the intervention and 6 weeks after the intervention

### Method of measurement

Expanded Disability Status Scale

2

### Description

Quality of Life

### Timepoint

Before the intervention and 6 weeks after the intervention

### Method of measurement

Multiple Sclerosis Quality of Life-54 Questionnaire

## Intervention groups

1

### Description

Intervention group: The first group will be treated with N-acetylcysteine tablets (Exir Company) at a dose of 600 mg every 12 hours.

### Category

Treatment - Drugs

2

### Description

Intervention group: The second group will receive Amantadine Capsules, brand Amorel (Amin Company) at a dose of 100 mg every 12 hours.

## Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Golestan Hospital MS Society

#### Full name of responsible person

Fatemeh Ghasemi

#### Street address

Farvardin Blvd., Golestan Hospital, MS Society

#### City

Ahwaz

#### Province

Khuzestan

#### Postal code

3311861357

#### Phone

+98 61 3374 3012

#### Email

fatemeh.ghasemi2280@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences

#### Full name of responsible person

Mehdi Ahmadi Moghadam

#### Street address

University City, Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences and Health Services

#### City

Ahwaz

#### Province

Khuzestan

#### Postal code

6135715794

#### Phone

+98 61 3333 3477

#### Email

research@ajums.ac.ir

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Vice Chancellor for Research and Technology, Ahvaz Jundishapur 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**

Fatemeh Ghasemi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Neurology

**Street address**

Farvardin Blvd., Golestan Hospital, Neurology  
Department

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

3311861357

**Phone**

+98 61 3374 3012

**Fax**

**Email**

fatemeh.ghasemi@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Fatemeh Ghasemi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Neurology

**Street address**

Farvardin Blvd., Golestan Hospital, Neurology  
Department

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

3311861357

**Phone**

+98 61 3374 3012

**Fax**

**Email**

fatemeh.ghasemi@gmail.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Fatemeh Ghasemi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Neurology

**Street address**

Farvardin Blvd., Golestan Hospital, Neurology  
Department

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

3311861357

**Phone**

+98 61 3374 3012

**Fax**

**Email**

fatemeh.ghasemi@gmail.com

**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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

After defending the dissertation and approval by Ahwaz University of Medical Sciences, the collected data will be fully available (after identifying the participants) to researchers and patients.

**When the data will become available and for how long**

Access period starts 6 months after the results are published

**To whom data/document is available**

If requested, the results will be available to other researchers working in academic and scientific institutions.

**Under which criteria data/document could be used**

The information of this trial will be provided to researchers and patients with the aim of improving the

quality of life of patients with multiple sclerosis.

**From where data/document is obtainable**

Receiving documents will be possible by sending an email to the person in charge of the update.

**What processes are involved for a request to access data/document**

Documents will be emailed over a 15-day period.

**Comments**