Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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., Ahvaz, Golestan Hospital

City

Ahwaz

Province

Khouzestan

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
Khouzestan
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
Khouzestan
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

Khouzestan

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

Khouzestan

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

Khouzestan

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