

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of N-acetylcysteine on nitric oxide, oxidative stress biomarkers, depression and stress in patients with multiple sclerosis

Protocol summary

Study aim

Effect of N-acetylcysteine on nitric oxide, oxidative stress biomarkers, depression and stress in patients with MS

Design

The present study is a double blind phase 3 randomized clinical trial and will be carried out on 60 patients with multiple sclerosis.

Settings and conduct

The present study is a double-blind clinical trial with the aim of evaluating the effect of N-acetylcysteine on nitric oxide, oxidative stress biomarkers, depression and stress in patients with multiple sclerosis at MS Society of Khuzestan province. Physician, researcher, patient and data analyst is not aware of the type of the treatment.

Participants/Inclusion and exclusion criteria

Patients with multiple sclerosis more than 2 years; EDSS less than 4.5; patients without current diagnosis of other inflammatory or autoimmune disease; the age range is between 18-60 years old; not taking depression or anxiety drugs score of 10-30 (mild to moderate depression) from Beck questionnaire and 15-25 (mild to moderate anxiety) from DASS21 questionnaire; tendency to participate in the study. Exclusion criteria: clinical relapses within 3 months before or during the study; pregnancy or lactation; cardiovascular diseases; patients with blood pressure disorders; liver and kidney disease; bronchospasm; asthma and any respiratory failure; gastric ulcer; bleeding and impaired blood coagulation; those who are allergic to NAC and any combination it contains; taking antioxidants or NAC over the past 60 days smoking; alcohol and drugs abuse; stressful events during the study.

Intervention groups

Intervention group: N-acetylcysteine effervescent tablets, 1200 milligram daily, 2 times per day, 600 milligram tablet each time, for 60 days. Zambon Pharma Co, switzerland. Control group: placebo, 2 times per day, 600 milligram tablet each time, for 60 days. Osveh Pharma Co, Iran.

Main outcome variables

Serum GSH; MDA; TAC and NO; depression and anxiety (questionnaire)

General information

Reason for update

Acronym

The effect of NAC in the treatment of patients with MS

IRCT registration information

IRCT registration number: **IRCT20180515039662N1**

Registration date: **2018-06-03, 1397/03/13**

Registration timing: **prospective**

Last update: **2018-06-03, 1397/03/13**

Update count: **0**

Registration date

2018-06-03, 1397/03/13

Registrant information

Name

Golsa Khalatbari mohseni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3373 8253

Email address

Khalatbari.g@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-20, 1397/03/30

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of N-acetylcysteine on nitric oxide, oxidative stress biomarkers, depression and stress in patients with multiple sclerosis

Public title

The effect of N-acetylcysteine in the treatment of multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with multiple sclerosis more than 2 years EDSS $\leq 4/5$ Patients without current diagnosis of other inflammatory or autoimmune disease The age range is between 18-60 years Not taking depression or anxiety drugs Score of 10-30 (mild to moderate depression) from Beck Depression questionnaire in depression subscale and 15-25 (mild to moderate anxiety) from DASS21 questionnaire Tendency to participate in the study

Exclusion criteria:

Clinical relapses within 3 months before or during the study Pregnancy and lactation Cardiovascular diseases Patients with blood pressure disorders Liver and kidney disease Bronchospasm, asthma and any respiratory failure Gastric ulcer Bleeding and impaired blood coagulation Those who are allergic to NAC and any combination it contains, Taking antioxidants or NAC over the past 60 days Smoking, alcohol or drugs abuse Stressful events during the study

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

A total of 60 people will be assigned by block randomization to two groups (30 in the intervention group and 30 in the placebo group) and 10 blocks will be created. Random numbers will be generated randomly by random allocation software.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double blind study the jars containing the tablets

will be the same and neither the patients nor researcher know which tablets are being received. In fact, a third person who knows the contents of the jars distributes them among the participants. The shape and size of the tablets are similar in both groups, while their content is different.

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

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

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Postal code

61357-15794

Approval date

2018-01-20, 1396/10/30

Ethics committee reference number

IR.AJUMS.REC.1396.888

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**

Glutathione

Timepoint

The beginning of the study- The end of the study

Method of measurement

Spectrophotometry

2

Description

Malondialdehyde

Timepoint

The beginning of the study- The end of the study

Method of measurement

Spectrophotometry

3

Description

Total antioxidant capacity

Timepoint

The beginning of the study- The end of the study

Method of measurement

Spectrophotometry

4

Description

Nitric oxide

Timepoint

The beginning of the study- The end of the study

Method of measurement

Spectrophotometry

5

Description

Depression

Timepoint

The beginning of the study- The end of the study

Method of measurement

Beck questionnaire

6

Description

Anxiety

Timepoint

The beginning of the study- The end of the study

Method of measurement

DASS 21 questionnaire

Secondary outcomes

1

Description

Body Mass Index

Timepoint

The beginning of the study- The end of the study

Method of measurement

Body weight / high square (kg/m²)

2

Description

Dietary intake

Timepoint

The beginning of the study- The end of the study

Method of measurement

Three-day record

Intervention groups

1

Description

Intervention group: 30 patients with multiple sclerosis will receive 600 mg N-acetylcysteine effervescent tablet (Zambon Pharma Co, Switzerland) twice daily within 12 hours (1200 mg daily) after being dissolved in warm water, for 60 days to be taken before meals. To control the correct use of medicines, pills are given to patients every 2 weeks and the empty blisters of pills are collected and counted. If a patient did not consume more than 20% of tablets, he would be excluded.

Category

Treatment - Drugs

2

Description

Control group: 30 patients with multiple sclerosis will receive one effervescent tablet (similar to 600 mg N-acetylcysteine effervescent tablet in terms of shape, colour and flavour) 2 times a day within 12 hours, after being dissolved in warm water, for 60 days to be taken after meals. The placebo will be produced at the Osveh Pharma Co, Iran with the following formulation: micro-crystalline cellulose, corn starch, sorbitol and talk. To control the correct use of placebo, pills are given to patients every 2 weeks and the empty blisters of pills are collected and counted. If a patient did not consume more than 20% of tablets, he would be excluded.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Multiple sclerosis Society of Khoozestan

Full name of responsible person

Dr. Nastaran Madjdinasab

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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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

Golsa Khalatbari Mohseni

Position

Msc Student

Latest degree

Master

Other areas of specialty/work

Nutrition

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Latest degree

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Latest degree

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Email

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

it is not the objective of this study.

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