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 ≤ 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 subscal 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
City
Ahvaz
Province
Khouzestan
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 / hight 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 ptients with multiple sclerosis will received 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 befor meals .to control the correct use of medicins, 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 exclouded.
Category
Treatment - Drugs

2

Description
Control group: 30 ptients with multiple sclerosis will received 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 fallowing 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 exclouded.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Multiple sclerosis Society of Khoozestan
Full name of responsible person
Dr. Nastaran Madjdinasab
Street address
Faculty of Rehabilitation, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd., Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
15794-61357
Phone
+98 61 3374 3660
Email
n.majdinasab@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Badavi
Street address
Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd., Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Phone
+98 61 3336 7570
Fax
+98 61 3336 1544
Email
badavi-m@ajums.ac.ir
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
Street address
Faculty of Paramedicine, Jundishapur University of Medical Sciences
City
Ahvaz
Province
Khouzestan
Postal code
6135815751
Phone
-
Email
Khalatbari.g@ajums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Dr. Seyed Ahmad Hosseini
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Biochemistry
Street address
Paramedical School, Ahvaz Jundishapur University of Medical Sceinces, Golestan Blvd., Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Phone
Fax
Email
Seyedahmadhosseini@yahoo.com

Person responsible for updating data

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
Street address
Faculty of Paramedicine, Jundishapur University of Medical Sciences
City
Ahvaz
Province
Khouzestan
Postal code
6135815751
Phone
+98 61 3321 4581
Email

khalatbari.g@ajums.ac.ir

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