Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the Effects of Glutathione on Cognitive and Motor Functions and Clinical Progression Indicators in Patients with Multiple Sclerosis.

Protocol summary

Study aim
To evaluate the effect of glutathione on motor function, cognitive function, fatigue severity, and disease progression in patients with multiple sclerosis.

Design
A randomized, double-blind, controlled clinical trial with 60 participants. Randomization was performed using the RAND function in Microsoft Excel. The study includes an intervention group and a control group.

Settings and conduct
Randomized, double-blind, placebo-controlled trial in 60 RRMS patients. Participants receive glutathione 500 mg or placebo for 12 weeks. EDSS, Fatigue Scale, SSST, 9-HPT, and TMT are assessed at baseline and study end. Patients and assessors are blinded

Participants/Inclusion and exclusion criteria
Inclusion Criteria: "Confirmed diagnosis of Multiple Sclerosis according to the 2023 McDonald criteria Age 18–50 years Expanded Disability Status Scale (EDSS) score ≤ 6.5 Provision of written informed consent for participation in the study Exclusion criteria: "History of infection or hospitalization within the previous two weeks "History of a multiple sclerosis relapse within the previous two weeks "Severe cognitive impairment or psychosis

Intervention groups
Sixty patients with relapsing-remitting multiple sclerosis will be randomly assigned to two groups. The intervention group (n=30) will receive oral glutathione 500 mg daily for 12 weeks in addition to routine treatment, while the control group (n=30) will receive a matching placebo for 12 weeks in addition to routine treatment.

Main outcome variables
Change in EDSS score; Change in Fatigue Scale score; Change in Six Spot Step Test (SSST) performance; Change in Nine-Hole Peg Test (9-HPT) performance; Change in Trail Making Test (TMT) performance

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20260520069465N1**
Registration date: **2026-06-01, 1405/03/11**
Registration timing: **prospective**

Last update: **2026-08-10, 1405/05/19**
Update count: **1**

Registration date
2026-06-01, 1405/03/11

Registrant information
Name
Esmat Ramezanirad
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Iran (Islamic Republic of)
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Recruitment status
recruiting
Funding source

Expected recruitment start date
2026-08-27, 1405/06/05
Expected recruitment end date
2026-11-26, 1405/09/05
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Evaluation of the Effects of Glutathione on Cognitive and Motor Functions and Clinical Progression Indicators in Patients with Multiple Sclerosis.

Public title
Effect of Glutathione on patients with Multiple Sclerosis.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of Multiple Sclerosis Provision of written informed consent by the patient for participation in the study
Exclusion criteria:
Patients with severe cognitive impairment or psychosis. Acute or chronic infection or inflammation during the two weeks prior to study enrollment. History of head trauma within the previous two weeks. History of hospitalization within the previous two weeks. History of a multiple sclerosis relapse within the previous two weeks. Pregnancy Breast feeding
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization
Blinding (investigator's opinion)
Double blinded
Blinding description
This study will be conducted as a double-blind clinical trial. Neither the participants nor the investigators/outcome assessors will be aware of the treatment allocation. Glutathione and placebo will be prepared in identical formulations, packaging, appearance, and labeling. Treatment codes will be kept confidential by an independent third party and will not be disclosed until completion of data collection and analysis, except in cases of medical emergency."
Placebo
Used
Assignment
Single
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
Neurology Ward, Golestan Hospital,Golestan Blv.,Ahvazd
City
Ahvaz
Province
Khouzestan
Postal code
6135733117
Approval date
2026-02-23, 1404/12/04
Ethics committee reference number
IR.AJUMS.REC.1404.646

Health conditions studied

1

Description of health condition studied
Multiple Sclerosis
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Change in Expanded Disability Status Scale (EDSS) score
Timepoint
At the baseline and at the end of study(after 12 weeks of study)
Method of measurement
Disease disability progression will be assessed using the Expanded Disability Status Scale (EDSS). EDSS scores will be recorded at baseline and after 12 weeks of treatment by a neurologist, and changes will be compared between the two groups.

Secondary outcomes

1

Description
Change in Fatigue Scale score
Timepoint
from baseline to the end of the 12-week treatment period.
Method of measurement
Fatigue severity will be measured using the Fatigue Scale questionnaire.

2

Description
2. Change in completion time of the Six Spot Step Test (SSST)
Timepoint
from baseline to the end of the 12-week treatment period
Method of measurement
Lower extremity motor function will be assessed by recording the completion time of the Six Spot Step Test (SSST).

3

Description
Change in completion time of the Nine-Hole Peg Test (9-HPT) as a measure of upper extremity motor function.
Timepoint
from baseline to the end of the 12-week treatment period
Method of measurement
Upper extremity motor function will be assessed by recording the completion time of the Nine-Hole Peg Test (9-HPT).

4

Description
Change in completion time of the Trail Making Test (TMT) as a measure of cognitive function.
Timepoint
from baseline to the end of the 12-week treatment period.
Method of measurement
Cognitive function will be assessed by recording the completion time of the Trail Making Test (TMT).

Intervention groups

1

Description
Intervention Group: Thirty patients with relapsing-remitting multiple sclerosis will receive oral glutathione 500 mg once daily for 12 weeks in addition to their routine treatment.Control Group: Thirty patients with relapsing-remitting multiple sclerosis will receive a placebo identical in appearance and packaging to glutathione once daily for 12 weeks in addition to their routine treatment.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Golestan Hospital of Ahvaz
Full name of responsible person
Esmat Ramezanirad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Vice Chancellor for Research and Technology Ahvaz Jundishapur University
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Research and Technology Building.Ahvaz Jundishapur University of Medical Sciences.Farvardin Blvd.Golestan District.Ahvaz.Iran
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
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
Esmat Ramezanirad
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Neurology
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Person responsible for updating data

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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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Title: Research Data on the Effects of Glutathione on Cognitive Function, Motor Function, and Clinical Progression in Patients with Multiple Sclerosis Details: De-identified participant data, including EDSS scores, Fatigue Scale scores, and results of the Trail Making Test (TMT), Nine-Hole Peg Test (9-HPT), and Six Spot Step Test (SSST) at baseline and after 12 weeks of treatment, will be collected. The data may be made available after publication of the study results in accordance with research ethics regulations and while maintaining participant confidentiality.
When the data will become available and for how long
De-identified study data will be available after publication of the study results without a time limit, subject to research ethics regulations and participant confidentiality.
To whom data/document is available
Qualified researchers upon reasonable request and approval by the principal investigator
Under which criteria data/document could be used
The de-identified data may be used for scientific research, secondary analyses, systematic reviews, and meta-analyses related to multiple sclerosis. Access to the data will be granted upon reasonable request, approval by the principal investigator, and compliance with research ethics regulations and participant confidentiality requirements.
From where data/document is obtainable
Requests for access to study data and related documents should be directed to the principal investigator

Department of Neurology Ahvaz Jundishapur University of Medical Sciences Ahvaz Iran.

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

Requests for access to study data and related documents should be submitted in writing to the principal investigator. Requests will be reviewed by the research team, and access may be granted upon approval while ensuring participant confidentiality and data protection.

Comments