Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of epigallocatchin gallate Enriched Green Tea on some Clinical, Inflammatory, Antioxidant and Cognitive Parameters in Patients with Multiple Sclerosis; A Triple-blind Randomized Placebo Clinical Trial

Protocol summary

Study aim

Determining the effect of EGCG-enriched green tea on some clinical, inflammatory, antioxidant, and cognitive parameters and quality of life in patients with multiple sclerosis

Design

A controlled, parallel-group, triple-blind, block-randomized clinical trial was conducted on 40 patients.

Settings and conduct

The target population of which was people with MS who referred to the Rafsanjan Center for Special Diseases. The three blind subjects: the patient, the researcher and the administrator, the examiner, and the data analyst were blinded to the medication used.

Participants/Inclusion and exclusion criteria

Inclusion criteria included willingness to participate in the study and having relapsing-remitting MS. Exclusion criteria included allergy to green tea or green tea components and products, use of any antioxidant supplements, daily consumption of green tea before the start of the study, following a special diet, participation in another study, alcohol consumption, drug and opium use, pregnancy and breastfeeding, neurological and autoimmune diseases, and cancer.

Intervention groups

The subjects in the green tea and placebo groups consumed 2 capsules of EGCG-enriched green tea powder or placebo daily for 3 months while maintaining their usual diet. The dosage was 2 capsules daily, preferably one capsule every 12 hours. The selected dose was such that each subject received approximately 240 mg of the active ingredient EGCG (epigallocatechin gallate) daily.

Main outcome variables

Cognitive function: depression; fatigue; overt and covert anxiety; brief mental state; and auditory information processing speed and working memory.

General information

Reason for update

Acronym

MS

IRCT registration information

IRCT registration number: **IRCT20180902040927N6**

Registration date: **2026-05-14, 1405/02/24**

Registration timing: **retrospective**

Last update: **2026-05-14, 1405/02/24**

Update count: **0**

Registration date

2026-05-14, 1405/02/24

Registrant information

Name

Mahdieh Azin

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3131 5072

Email address

m.azin@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-06, 1399/07/15

Expected recruitment end date

2021-09-23, 1400/07/01

Actual recruitment start date

2021-06-22, 1400/04/01

Actual recruitment end date

2022-07-23, 1401/05/01

Trial completion date

2022-12-01, 1401/09/10

Scientific title
The Effect of epigallocatchin gallate Enriched Green Tea on some Clinical, Inflammatory, Antioxidant and Cognitive Parameters in Patients with Multiple Sclerosis; A Triple-blind Randomized Placebo Clinical Trial

Public title
Studying the effect of green tea in MS patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Willingness to participate Confirmation of Relapsing-Remitting Multiple Sclerosis (RRMS) according to the McDonald protocol Expanded Disability Status Scale (EDSS) score below 3.5 Age 20–50 years

Exclusion criteria:
Having other neurological and autoimmune diseases Having cancer Allergy to green tea products Current use of antioxidant supplements Regular green tea consumption Adherence to special diets Alcohol or substance abuse Pregnancy and lactation.

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked

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

Sample size
Target sample size: **48**
Actual sample size reached: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants were randomly assigned to green tea and placebo groups using a 1:1 allocation ratio using a block randomization method. The randomization sequence was generated using SPSS software, and blocks of size 4 were used to maintain a balance between the numbers of subjects in the two groups throughout the study. In order to maintain allocation concealment, the allocation sequence was placed in sealed, numbered envelopes so that the assigned group could not be predicted when each participant entered the study.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Green tea and placebo capsules were delivered to the researcher in identical cans and packaging from Essans Daru Company. Only the numbers 1 and 2 were written on the cans of the capsules. None of the researchers, project managers, data analysts, outcome assessors, care provider, and participants (patients) knew which drug each number corresponded to. Data analysis was also performed in two groups, 2 and 1, and Essans Daru Company was asked about the type of drug when writing the results. In this study, the safety monitoring committee was not relevant.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Rafsanjan University of Medical Sciences

Street address
Imam Ali Boulevard, Central Organization, Building No. 3, Deputy for Research and Technology

City
Rafsanjan

Province
Kerman

Postal code
7717933777

Approval date
2020-06-15, 1399/03/26

Ethics committee reference number
IR.RUMS.REC.1399.063

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
Cognitive function: working memory and auditory information processing speed

Timepoint
Before the start of the study and 3 months after receiving the drug

Method of measurement
Paced Auditory Serial Addition Test

2

Description
Overt and covert anxiety
Timepoint
Before and after three months of taking the drug
Method of measurement
Spielberger Overt and Covert Anxiety Questionnaire

3

Description
Scale of Mini mental status test (MMSE)
Timepoint
Before and 3 months after the intervention
Method of measurement
Mini mental status test (MMSE)

4

Description
Depression rate
Timepoint
Before and 3 months after the intervention
Method of measurement
Beck Depression Inventory- II (BDI- II)

5

Description
Degree of fatigue
Timepoint
Before and 3 months after the intervention
Method of measurement
Fatigue Severity Scale: (FSS)

Secondary outcomes

1

Description
Interleukin 10
Timepoint
Before the start of the intervention and three months after the start of the intervention
Method of measurement
Karmania Pars Gene Company Kit

2

Description
Total antioxidant capacity (TAC)
Timepoint
Before the start of the intervention and three months after the start of the intervention
Method of measurement
Karmania Pars Gene Company Kit

3

Description
Lower limb motor function assessment
Timepoint
Before the start of the intervention and three months after the start of the intervention
Method of measurement
Timed 25-Foot Walk (T25-FW)

4

Description
Upper limb motor function assessment
Timepoint
Before the start of the intervention and three months after the start of the intervention
Method of measurement
Nine-Hole Peg Test

5

Description
The degree of disability of the MS patient
Timepoint
Before the start of the intervention and three months after the start of the intervention
Method of measurement
Expanded Disability Status Scale (EDSS)

6

Description
Quality of life
Timepoint
Before the start of the intervention and three months after the start of the intervention
Method of measurement
36-item Quality of Life Questionnaire (SF-36)

Intervention groups

1

Description
Control group: To receive capsules containing vegetable cellulose, magnesium stearate, silica or maltodextrine as a placebo twice daily for 3 months
Category
Placebo

2

Description
Intervention group: To receive 60 mg capsules containing green tea enriched with 40% effective epigallocatechin gallate twice daily for 3 months
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Specific Diseases Center of Ali Ibn Abi Taleb Hospital

Full name of responsible person
Ali Riyahi
Street address
Ali Ibn Abi Talib Square
City
Rafsanjan
Province
Kerman
Postal code
7717937555
Phone
+98 34 3428 0022
Email
aliebn_hospital@rums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Hamid Hakimi
Street address
Imam Ali Boulevard
City
Rafsanjan
Province
Kerman
Postal code
7717933777
Phone
+98 34 3428 0038
Email
info@rums.ac.ir
Grant name
Rafsanjan University of Medical Sciences
Grant code / Reference number
98136
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rafsanjan University of Medical Sciences
Proportion provided by this source
80
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
Rafsanjan University of Medical Sciences
Full name of responsible person
Mahdieh Azin
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Neuroscience
Street address
No. 44, Pasdaran 2 Street
City
Rafsanjan
Province
Kerman
Postal code
۷۷۱۷۶۳۷۳۱۸
Phone
+98 34 3131 5072
Email
mahdieh.azin@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Mahdieh Azin
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Neuroscience
Street address
No. 44, Pasdaran 2 Street
City
Rafsanjan
Province
Kerman
Postal code
7717637318
Phone
+98 34 3131 5072
Email
mahdieh.azin@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Mahdieh Azin
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Neuroscience
Street address

No. 44, Pasdaran 2nd Street
City
Rafsanjan
Province
Kerman
Postal code
7717637318
Phone
+98 34 3131 5072
Email
mahdieh.azin@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
Not applicable
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
The main consequence after de-identifying individuals is that they can be shared.
When the data will become available and for how long
Access period begins one year after results are published.
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
For meta-analysis studies
From where data/document is obtainable
Mahdieh Azin by email: mahdieh.azin@gmail.com
What processes are involved for a request to access data/document
The application process must be formal, from an academic researcher. The purposes of using the data must be clearly explained. A reference to the published article must be provided.
Comments