Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of Centella asiatica L. on cognitive impairments in patients with multiple sclerosis (MS)

Protocol summary

Study aim

The effect of centella asiatica L. on cognitive disorders in patients with multiple sclerosis by evaluating the changes in the BICAMS (brief international cognitive assessment for MS) test in patients referred to the MS clinic of Shafa-Kerman Hospital.

Design

This double-blind randomized clinical trial, investigated the effectiveness of Centella asiatica on cognitive disorders of patients with MS. Dividing the patients into two equal groups, intervention and control, was done using the quadruple random block method.

Settings and conduct

This research was conducted in the MS clinic of Shafa-Kerman Hospital on at least 96 patients with MS with cognitive impairment. After packaging, the drug and placebo were coded as A and B by the pharmacist. These codes were attached with a label on the drug and placebo package, and only the pharmacist and the biostatistician knew how to assign these codes to the drug and placebo. Then they were provided to the researcher. Neither the researcher nor the patient knew how to assign the codes to the drug or placebo. Finally, the codes and data are given to the statistician and the analysis is done.

Participants/Inclusion and exclusion criteria

Inclusion criteria: -MS patients with complaints of cognitive impairment referred to the MS clinic and cognitive impairment was proven based on the BICAMS test. Exclusion criteria: -suffering from psychiatric diseases such as severe depression and schizophrenia, etc. -pregnancy

Intervention groups

The drug group received 500 mg capsules containing centella asiatica plant powder and the placebo group received 500 mg capsules containing starch.

Main outcome variables

severity of cognitive impairment; Quality of Life

General information

Reason for update

Acronym

MS

IRCT registration information

IRCT registration number: **IRCT20161108030776N5**
Registration date: **2024-06-15, 1403/03/26**
Registration timing: **retrospective**

Last update: **2024-06-15, 1403/03/26**
Update count: **0**

Registration date

2024-06-15, 1403/03/26

Registrant information

Name

Mohadese Kamali

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-06, 1401/05/15

Expected recruitment end date

2022-12-05, 1401/09/14

Actual recruitment start date

2022-08-23, 1401/06/01

Actual recruitment end date

2023-03-30, 1402/01/10

Trial completion date

2023-05-31, 1402/03/10

Scientific title
The effect of Centella asiatica L. on cognitive impairments in patients with multiple sclerosis (MS)

Public title
The effect of Centella asiatica L. on cognitive disorders in MS

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Multiple sclerosis patients with complaints of cognitive impairment referred to the MS clinic and had proven cognitive impairment based on the BICAMS (brief international cognitive assessment for MS) test.

Exclusion criteria:
Suffering from psychiatric diseases such as severe depression, schizophrenia, etc. pregnancy breastfeeding

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **96**
Actual sample size reached: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
Dividing the patients into two equal intervention and control groups was done using the quadruple random block method. The codes of the patients were provided to the biostatistics specialist and were not opened until the end of the intervention period of the last patient and the analysis.

Blinding (investigator's opinion)
Double blinded

Blinding description
After packaging, the drug and placebo were coded as A and B by the pharmacist. These codes were attached with a label on the drug and placebo package, and only the pharmacist and the biostatistician knew how to assign these codes to the drug and placebo. Then they were provided to the researcher. Neither the researcher nor the patient knew how to assign the codes to the drug or placebo. Finally, the codes and data are given to the statistician and the analysis is done.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Kerman University of Medical Sciences

Street address
University of Medical Sciences campus, the beginning of Haft Bagh Alavi axis

City
Kerman

Province
Kerman

Postal code
7616913555

Approval date
2022-04-16, 1401/01/27

Ethics committee reference number
IR.KMU.REC.1401.048

Health conditions studied

1

Description of health condition studied
Multiple sclerosis (MS)

ICD-10 code
G35-G37

ICD-10 code description
Demyelinating diseases of the central nervous system

Primary outcomes

1

Description
severity of cognitive impairment

Timepoint
Investigation of cognitive impairment at the beginning of the study (before the start of the intervention) and two months after the start of the intervention with the Centella asiatica

Method of measurement
BICAMS questionnaire

2

Description
Quality of Life

Timepoint
At the beginning of the study (before the start of the intervention) and two months after the start of Centella Asiatica

Method of measurement
MSQOL54 questionnaire

Secondary outcomes

1

Description
Possible side effects
Timepoint
At the end of the study
Method of measurement
Registration by the patient and questions from the patient

Intervention groups

1

Description
Intervention group: Every 12 hours after meals, they received a capsule containing Centella asiatica plant powder for two months.
Category
Treatment - Drugs

2

Description
Control group: Every 12 hours after meals, they received a capsule containing starch, which is exactly the same as the drug group, for two months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shafa hospital
Full name of responsible person
Hoda Kamali
Street address
Shafa Medical Education Center, Kausar Blvd.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Abedin Iranpoor
Street address
Research and Technology Office, at the beginning of Ibn Sina Street, Samiya Crossroads (Tahmasababad)
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iranpourabedin89@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Mohadese Kamali
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Traditional Medicine
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Person responsible for scientific inquiries

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Position

Assistant Professor

Latest degree

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available

Title and more details about the data/document

Through the email of the person responsible for the general or scientific response of the study

When the data will become available and for how long

After printing and publishing the article

To whom data/document is available

Researchers in the specialized fields of neurology and Persian medicine

Under which criteria data/document could be used

On the condition of maintaining trust and citation

From where data/document is obtainable

Correspond with the email of the person responsible for the general or scientific response of this study.

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

Correspondence with the email of the person responsible for the general or scientific response of this study

Comments