Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

The effect of lavender tea on the ataxia and spasm in patients with multiple sclerosis

Protocol summary

Study aim
The effect of lavender extract hydroalcoholic extract on ataxia and spasm in patients with multiple sclerosis.

Design
This clinical trial randomized with software; single blind in which 84 patients with multiple sceloresis with inclusion criteria divided into two groups of intervention and control.

Settings and conduct
This study is performed on referrer to Kashani and Hajar hospitals in Shahrekord in single blind. the patient chooses one of the two drugs randomly and the name of each person and the code of the drug provided to him by the secretary is registered and neither the patient nor the researcher has any information about the type of medication. And only when analyzing the data will the names of each individual and his drug be identified to complete the information profile of the patients by mentioning the name of the drug received by them. In that tester, they do not know the type of drug received. The intervention group received one herbal tea (manufactured by Kohgel Company) and the control group received one placebo tea for 60 days daily.

Participants/Inclusion and exclusion criteria
Age between 20 and 50 years, diagnosis of MS, obtaining a score of 3-5 in disability severity scale (EDSS), and stable spasticity with the score ≥2 for one of the joints on the Ashworth scale. Also, the presence of ataxia, lack of neurological deficits (other than MS), cardiovascular disease, infectious diseases, and lack of exacerbation of clinical symptoms of MS. eclusion criteria: dissatisfaction with cooperation, drug sensitivity and drug use other than prescribed medications

Intervention groups
The intervention group received one herbal tea (manufactured by Kohgel Company) and the control group received one placebo tea for 60 days daily.

Main outcome variables
ataxia, spasm

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220818055740N1**
Registration date: **2022-09-11, 1401/06/20**
Registration timing: **retrospective**

Last update: **2022-09-11, 1401/06/20**
Update count: **0**

Registration date
2022-09-11, 1401/06/20

Registrant information

Name
Nahid Jivad

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 38 3335 1031

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jivad@skums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-14, 1398/04/23

Expected recruitment end date
2019-09-14, 1398/06/23

Actual recruitment start date
2019-07-14, 1398/04/23

Actual recruitment end date
2019-09-14, 1398/06/23

Trial completion date
2022-09-11, 1401/06/20

Scientific title

The effect of lavender tea on the ataxia and spasm in patients with multiple sclerosis

Public title

The effect of lavender tea on the ataxia and spasm in patients with multiple sclerosis

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria: age between 20 and 50 years, diagnosis of MS disease, scoring 3-5 on the Disability Severity Scale (EDSS), and the presence of stable spasticity with a score of ≥ 2 for one of the joints on the Ashurt scale, the presence of ataxia, and the absence of neurological defects.(other than MS), cardiovascular, infectious diseases, no exacerbation of clinical symptoms of MS, no treatment with steroids two months before entering the study.

Exclusion criteria:

Exclusion criteria: dissatisfaction to cooperation, sensitivity to drugs and consumption of drugs other than prescribed drugs.

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **84**

Actual sample size reached: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

The random allocation of the participants to the intervention and control groups will be done using random allocation software. Then, some envelopes will be prepared according to the number of participants in the study. Then number 1 will be recorded on the first envelope, number 2 on the second envelope, and etc. The sequence of assignment of the participants will be determined by the software and each assignment will be put inside each envelope respectively. At the time of study , the specified envelope for each individual will be opened and the individual will be assigned to one of the intervention and control groups according to the option recorded inside the envelope.

Blinding (investigator's opinion)

Single blinded

Blinding description

The single blindness of the study was that the mentioned drugs received code without any labels and the patient selected one of the two drugs randomly. Then, the name of each person and the drug code provided to him registered by the secretary. Neither the patient nor the doctor knew the type of medication, and only when analyzing the data, the names of each person and his drug were specified and completed the patients' information profile by mentioning the name of the drug received by them.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahrekord University of Medical Sciences

Street address

Kashani Blvd

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8818718791

Approval date

2020-07-22, 1399/05/01

Ethics committee reference number

IR.SKUMS.REC.1398.078

Health conditions studied

1

Description of health condition studied

Multiple sclerosis

ICD-10 code

G90-G99

ICD-10 code description

G90-G99

Primary outcomes

1

Description

multiple sclerosis

Timepoint

One month after intervention

Method of measurement

Spasticity was measured based on Ashworth scale and Spasm Repetition scale. Also, ataxy was measured by Ataxi rating scale (ICARS) and Leaf BalanceTest (BSS).

Secondary outcomes

1

Description
Multiple sclerosis
Timepoint
One month after intervention
Method of measurement
Spasticity was measured based on Ashworth scale and Spasm Repetition scale. Also, ataxy was measured by Ataxi rating scale (ICARS) and Leaf BalanceTest (BSS).

Intervention groups

1

Description
Intervention group: Patients received lavender teain the intervention group for two months daily (Manufactured by Kogel Co.)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kashani Hospital Shahrekord
Full name of responsible person
Nahid Jivad
Street address
Kashani Hospital, Shahrekord University of Medical Sciences, Parastar Street, Shahrekord, Iran
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+98 38 3222 0016
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Dr Esfandiyar heydarian
Street address
Kashani Hospital of Shahrekord University of Medical Sciences,
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sadeghi.m@skums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Nahid Jivad
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Neurology
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Person responsible for scientific inquiries

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Position
Associate professor
Latest degree

Specialist

Other areas of specialty/work

Neurology

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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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

There is no further information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available