Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Studying the Effect of Cinnamon Oral Drop on Balance and Fear of Falling in Patients with Multiple Sclerosis Member of MS Association in Isfahan in 2018

Protocol summary

Study aim
Determining the Effect of Cinnamon Oral Drop on Balance and Fear of Falling in Patients with MS.

Design
Controlled Clinical Trial with Parallel and Triple Blind Patterns.

Settings and conduct
Patients with multiple sclerosis, members of the MS Society of Isfahan were studied during three months of study using 4 drops of cinnamon extract in three servings, and before the intervention and each month, they were assessed using Berg balance test and the Falls Efficacy Scale-International. In this research, the patients, the researcher, the person in charge of caring the patients and the statistical data analyst were blinded. The drugs and placebo were replicated in a laboratory environment under sterile conditions by a third party. There was no indication of the originality of drugs, and they were indicated by two groups of A and B.

Participants/Inclusion and exclusion criteria
The participants had multiple sclerosis (MS) according to the neurologist's diagnosis. The patients' age range was from 18 to 50 years. The patients had relapsing-remitting MS. The recorded disability measurement scale in the patients' file was from 5.1 to 6. Regular treatment was performed 4 weeks before the intervention. Patients agreed not to use alternative mmedications for 7 days before starting the intervention until the end of the intervention.

Intervention groups
The intervention group received 4 drops of cinnamon in three servings (morning, noon, and night) with a glass of tea, water, or milk, and the examinations were done using Berg Balance Scale and the fear of falling questionnaire. In the control group, the protocol was like the placebo group, and they received 4 drops of placebo per serving.

Main outcome variables
Consumption of Cinnamon oral drop; Balance; Fear of Falling

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190518043619N1**
Registration date: **2020-01-26, 1398/11/06**
Registration timing: **retrospective**

Last update: **2020-01-26, 1398/11/06**
Update count: **0**

Registration date
2020-01-26, 1398/11/06

Registrant information

Name
Soheila Moghimisarani

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-12-13, 1397/09/22

Expected recruitment end date
2019-07-22, 1398/04/31

Actual recruitment start date
2018-12-13, 1397/09/22

Actual recruitment end date
2019-07-22, 1398/04/31
Trial completion date
2019-07-22, 1398/04/31

Scientific title
Studying the Effect of Cinnamon Oral Drop on Balance and Fear of Falling in Patients with Multiple Sclerosis Member of MS Association in Isfahan in 2018

Public title
Studying the Effect of Cinnamon Oral Drop on Balance and Fear of Falling in Patients with Multiple Sclerosis (MS)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patient should be with Multiple Sclerosis based on the diagnosis of the neurologist. The patients' age range should be between 18 and 50 years old. The patients should be with relapsing-remitting MS. The recorded disability measuring scale in the patient's medical record should be ranged from 5.1 to 6. The patient should have permanent and regular treatment for 4 weeks before the intervention. The patient should agree not to use any alternative medications for 7 days prior to the intervention until the end of the intervention. The patients should not participate in regular exercises two months before the intervention. The help-seeker should be interested in participating in this research.
Exclusion criteria:
Being pregnant or intending to be pregnant or lacate during the intervention. Having liver and kidney dysfunction. Having cardiovascular or infectional diseases. Having allergy to cinnamon. Having neurological diseases in addition to Multiple Sclerosis. Having an experience of consuming alcohol or drug dependence.
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **60**
Actual sample size reached: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In the present study, available or easy sampling was used since all the samples were not available. Then, the samples with the inclusion criteria, after getting written consent by using a Random Picker Software from Play Store, which was already installed on the cellphone, and telling the help-seeker to hit the specified phone screen, were placed in Group A or B. 30 individuals were placed in the intervention group, and 30 were placed in the control group. During the intervention, 8 individuals in the intervention group and 5 in the control group were excluded due to the unwillingness to cooperate or relapse of the disease, that the researcher performed further sampling to replace them.
Blinding (investigator's opinion)
Triple blinded
Blinding description
It was necessary to prepare a 15 ml glass container for making placebo. Since the Cinnamon Drop lid had the logo of the manufacturer, twice of the lids were purchased to replace them. Glassware, cinnamon drops and mineral water were prepared for making placebo and homogenization, and were sent to the laboratory to perform homogenizing and coding without the presence of the researcher. In the laboratory, all the dishes and cabs (heads) were washed using dishwashing liquid and water and then were placed in an autoclave at 120℃ to ensure the process was sterile. By consulting to the pharmacist consultant and the Research Deputy of Medical Sciences of the University, 14.5 cc of mineral water and 5.5 cc of cinnamon drop were used by a dropper, and then labeled and coded. Labels of the dishes with cinnamon drop were washed and cleaned, and their lids were replaced, labeled and then coded; the placebo-making process was performed by a third party, and the researcher did not know whether the drugs were placebo or origin. Before getting the informed consent, the samples were informed that the probability of being placed in each of the intervention and control group was 50%, and if they were placed in the placebo group, it would be safe for them because placebo is a harmless material. At the end of the research, data analyzer and data evaluator were not aware of which groups A or B was the intervention group, and only the mark of A and B was used in the questionnaire to identify the groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Islamic Azad University, Khurasgan Branch, Isfahan
Street address
Islamic Azad University, Khurasgan Branch, Isfahan, University Blvd, East J Avenue., Arghavanieh, Isfahan
City
Isfahan
Province
Isfehan

Postal code
39998-81551
Approval date
2018-12-12, 1397/09/21
Ethics committee reference number
IR.IAU.KHUISF.REC.1397.151

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
Balance
Timepoint
At the beginning of the research, 1,2, and 3 months after using cinnamon orally.
Method of measurement
Berg Balance Scale

Secondary outcomes

1

Description
Fear of Falling
Timepoint
at the beginning of the study, 1,2, and 3 months after the study.
Method of measurement
effectiveness scale questionnaire in falling- international form.

Intervention groups

1

Description
Intervention group: Patients in the intervention group consumed 4 drops of cinnamon extract three times in a day (morning, noon, and night) with a glass of tea, water or milk, and examinations were performed using Berg balance scale and by fear of falling questionnaire on the first day, and at the end of the first, second, and third months.
Category
Treatment - Drugs

2

Description
Control group: Patients in control group consumed four drops of placebo in three servings (morning, noon, and night) with a glass of tea, water or milk, and examinations were done using Berg balance scale and the questionnaire of fear of falling on the first day, and at the end of first, second, and third months.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan MS Society
Full name of responsible person
Masoud Etemadifar
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
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
Islamic Azad University

Full name of responsible person
Sayedali Naji

Position
Lecturer

Latest degree
Subspecialist

Other areas of specialty/work
Nursery

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Position
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Latest degree
Master

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Nursery

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Latest degree
Master

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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
All the results and final data can be shared except for patient data and personal data with the principle of confidentiality in receiving information

When the data will become available and for how long
2019

To whom data/document is available
Researchers working in academia, people who are engaged in the industry, students, patients and all the individuals interested in obtainting data and documentation are permitted to request data and documentation.

Under which criteria data/document could be used
People are permitted to ask for any data and documentation except patients' personal information, by

observing the principle of confidentiality.

From where data/document is obtainable

Dr.Sayedali Naji; Islamic Azad University Isfahan (Khorasgan) Branch, University Blvd, Arqavanieh, Jey Street, Isfahan, Iran; a_naji@khuisf.ac.ir; 0098 9131150865 Soheila Moghimisarani; Islamic Azad University Isfahan (Khorasgan) Branch, University Blvd, Arqavanieh, Jey Street, Isfahan, Iran; s.moghimisarani@khuisf.ac.ir; 0098 9900076746

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

People can receive data and documentation by calling, sending emails, or meeting in person.

Comments