Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Determine the effect of caffeine on the ability to walk and balance in patients with multiple sclerosis

Protocol summary

Summary
Objective: To determine the effect of caffeine on the ability to walk and balance in patients with multiple sclerosis study design: double-blind, randomized, placebo-controlled study population with: a sample of 30 subjects with MS now at Ali ibn Abi Talib and the MS Society of Zahedan main criteria for inclusion:the sickness getting started More than 60 days ago؛ the lack of a history of allergy to caffeine exclusion criteria: any allergic reaction to caffeine, the study: the study involved 30 patients with multiple sclerosis: the effects of caffeine on gait and balance in patients with multiple sclerosis intervention time: three months, the primary outcome: progress in EDSS,TUG,MSWS-12,PGIC,BBS,MSIS-29 test score

General information

Acronym
MS
IRCT registration information
IRCT registration number: **IRCT2017012332142N1**
Registration date: **2017-03-27, 1396/01/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**
Registration date
2017-03-27, 1396/01/07

Registrant information
Name
afsoon dadvar
Name of organization / entity
medical university of zahedan
Country
Iran (Islamic Republic of)
Phone
+98 901 743 2529
Email address
afsoon.d@zaums.ac.ir

Recruitment status
Recruitment complete
Funding source
Vice chancellor for research,zahedan University of Medical Sciences

Expected recruitment start date
2017-03-10, 1395/12/20
Expected recruitment end date
2017-05-05, 1396/02/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Determine the effect of caffeine on the ability to walk and balance in patients with multiple sclerosis

Public title
The effects of caffeine on walking and balance in patients with multiple sclerosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: age-related diseases in the range of 20-55; has no history of patients without a history of allergy to caffeine; aggravates symptoms of MS patients weighing more than 40 kg; beginning 60 days prior to screening for exclusion criteria: If there is any a severe reaction to caffeine; if you see any progress in disease
Age
From **20 years** old to **55 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Using random blocks will be randomized

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of zahedan University of Medical Sciences
Street address
hesabi square-khalige fars bulvar- medical univercity of zahedan
City
zahedan
Postal code
98167-43463
Approval date
2016-12-18, 1395/09/28
Ethics committee reference number
IR.ZAUMS.REC.1395. 236 : کد اخلاقی طرح مربوطه/8029

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
The ability to walk and balance
Timepoint
Before intervention, 2, 4, 8 and 12 weeks after intervention
Method of measurement
Based on the results of the Kurtzke Expanded Disability Status Scale (EDSS), Twelve Item MS Walking Scale (MSWS-12), Patients' Global Impression of Change (PGIC), The Timed Up and Go (TUG) Test, Berg Balance SCALE (BBS) , Multiple Sclerosis Impact Scale (MSIS-29)

Secondary outcomes

1

Description
Drug Side Effects
Timepoint
If any discomfort in the patient of all time trials
Method of measurement
Registered on the basis of safety and tolerability based on AEs (see side effects) and SAEs (serious adverse events observed) and vital signs and electrocardiogram

Intervention groups

1

Description
Consumption of caffeine, the chemical composition: pure caffeine concentration: 100%, dose: 2.5 mg per kilogram of body weight on a daily basis (minimum dose), the frequency of use: once a day, duration of use: 3 months
Category
Other

2

Description
Substance: folic acid in the form of capsules that you're going to throw Caffeine, the chemical composition: folic acid, concentration: 100%, dosage: One mg, the frequency of use: once a day, duration: one month
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
MS Society of Zahedan
Full name of responsible person
Street address
City
zahedan

2

Recruitment center
Name of recruitment center
Ali ibn Abi Talib Hospital in Zahedan
Full name of responsible person
Street address

City
zahedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
zahedan University of Medical Sciences
Full name of responsible person
dr.mohsen tahery
Street address
Zahedan-square-hesabi doctor Persian Gulf Blvd. account-Medical Sciences and Health Services, Zahedan
City
zahedan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
zahedan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
zahedan University of Medical Sciences
Full name of responsible person
dr.hamed amirifard
Position
Neurologist-faculty at the zahedan University of Medical Sciences
Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
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Full name of responsible person
afsoon dadvar
Position
medical student
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00
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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty