

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

8029/مربوطه : کد اخلاقی طرح : IR.ZAUMS.REC.1395. 236

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

Street address

The doctor hesabi-Blvd. Persian Gulf-University of
Medical Sciences

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Person responsible for scientific inquiries

Contact

Name of organization / entity

zahedan University of Medical Sciences

Full name of responsible person

dr amiri fard

Position

Neurologist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

zahedan University of Medical Sciences

Full name of responsible person

afsoon dadvar

Position

medical student

Other areas of specialty/work

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00

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afsoond97@yahoo.com

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