Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Boswellia Serrata on Cognitive impairment in Multiple Sclerosis

Protocol summary

Summary
Boswellia Serrata (BS) had anti-inflammatory effects and neuroprotective activity. The aim of this study is to determine whether BS improves cognitive performance among patients with multiple sclerosis (MS) and cognitive impairment (CI). This double-blind, randomized, placebo-controlled trial compared BS 600 mg twice a day with placebo. 60 relapsing-remitting MS (RRMS) patients were selected (30 persons in each group), who had subjective cognitive complaints and the minimal assessment of cognitive function in MS (MACFIMS) was carried out, then after 2 months treatment duration, MACFIMS repeated again and the secondary results were recorded and analyzed.

General information

Acronym
-

IRCT registration information
IRCT registration number: **IRCT2015042021862N1**
Registration date: **2015-05-19, 1394/02/29**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date
2015-05-19, 1394/02/29

Registrant information
Name
Seiedeh Khatoun Mousavinejad
Name of organization / entity
Ahvaz Jundishapour University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 61 3375 4516
Email address
mousavinejad.skh@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source
Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date
2014-07-23, 1393/05/01
Expected recruitment end date
2015-03-20, 1393/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Boswellia Serrata on Cognitive impairment in Multiple Sclerosis

Public title
Effect of Boswellia Serrata on Cognitive impairment in Multiple Sclerosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Patients with Relapsing-Remitting MS (RRMS); Patients with cognitive impairment; Relapse free in the last 6 weeks before starting of assessments
Exclusion criteria: Current major depression; Preexisting medical or psychiatric disorders associated with cognitive dysfunction; Developmental disease; Drug or alcohol abuse, Patients with Expanded Disability Status Scale (EDSS)>3; New MS attacks and received corticosteroids up to 6 weeks before the study and pregnant or breastfeeding
Age
From **15 years** old to **56 years** old
Gender
Both

Phase
3

Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
-

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Commitee, Ahvaz Jundishapur University of Medical Sciences,
Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan street, Ahvaz
City
Ahaz
Postal code
6135715794
Approval date
2014-11-15, 1393/08/24
Ethics committee reference number
Ajums.REC.1393.261

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
Cognitive impairement
Timepoint
Before treatment, 2 months after treatment
Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Boswellia Serrata, 600 mg, twice a day, for 2 months
Category
Treatment - Drugs

2

Description
Placebo, twice a day, for 2 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
MS Clinic of Golestan hospital Ahvaz
Full name of responsible person
Seiedeh Khatoun Mousavinejad
Street address
Neurology ward, Golestan Hospital, Golestan street, Ahvaz
City
Ahaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz Jondishapour University of Medical Sciences
Full name of responsible person
Seyed Ahmad Hosseini
Street address
Research and Technology Management, Ahvaz Jundishapur University of Medical Sciences, Golestan street, Ahvaz
City
Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz Jondishapour 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

Ahvaz Judishapur University of Medical Sciences

Full name of responsible person

Siedeh Khatoun Mousavinejad

Position

Neurology Resident

Other areas of specialty/work

Street address

Neurology Ward, Golestan Hospital, Golestan street, Ahvaz

City

Ahvaz

Postal code

6135733118

Phone

+98 613374001

Fax

Email

mousavinejad.skh@ajums.ac.irmojtabanajafi2000@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz Judishapur University of Medical Sciences

Full name of responsible person

Siedeh Khatoun Mousavinejad

Position

Neurology resident

Other areas of specialty/work

Street address

Neurology ward, Golestan hospital, Golestan street, Ahvaz

City

Ahvaz

Postal code

6135733118

Phone

+98 613374001

Fax

Email

mousavinejad.skh@ajums.ac.irmojtabanajafi2000@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

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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