Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Double-blind placebo-controlled clinical trial of Boswellia serrata total extract on urinary disorders of multiple sclerosis patients

Protocol summary

Summary

The aim of this study is to evaluate the clinical effect of Boswellia serrata total extract on controlling urinary disorders of multiple sclerosis patients. It is a randomized, Double-blind, placebo-controlled and one central clinical trial. patients referred to Khuzestan MS Association who have urinary disorders (frequent urination, incontinence, urgency) (After filling consent forms and explaining the steps of the study for them) will fill a standardized questionnaire. They will be randomized to placebo and treatment groups. (34 patients in placebo and 34 in treatment group). For randomization drug and placebo boxes that are already encoded without the knowledge of researcher randomly one by one are removed and will be delivered to the person who is to receive medicine and and enters the room.patients in addition to daily treatment(receiving interferon and ...)will receive encoded pharmaceutical packaging.(2 capsules contain 300 mg placebo or frankincense daily). The duration of treatment will be 1 month. Standard questionnaire will be completed by the patient after treatment. The results of the questionnaires by the research team's neurologist will be evaluated and the results will be checked by a statistician. Inclusion criteria: People 15 to 65 years old; Patients with urinary disorders; patients without any other neurological disease such as stroke or psychiatric disease such as depression; patients without diabetes or any Autoimmune diseases such as lupus; in the past month,patients had no new attack and they have not received corticosteroid; studied women must not be pregnant exclusion criteria:the emergence of side effects; disease new attack;not using medication for a week; urinary tract infection which will be determined by paraclinical tests

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015071023144N1**
Registration date: **2015-09-15, 1394/06/24**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-09-15, 1394/06/24

Registrant information

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Double-blind placebo-controlled clinical trial of Boswellia serrata total extract on urinary disorders of multiple

sclerosis patients

Public title
Frankincense effect on urinary disorders in multiple sclerosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:People 15 to 65 years old; Patients with urinary disorders; patients without any other neurological disease such as stroke or psychiatric disease such as depression; patients without diabetes or any Autoimmune diseases such as lupus; in the past month,patients had no new attack and they have not received corticosteroid; studied women must not be pregnant exclusion criteria:the emergence of side effects; disease new attack;not using medication for a week; urinary tract infection which will be determined by paraclinical tests
Age
From **15 years** old to **65 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **68**
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
Research Development Deputy of Ahvaz Jundishapour University of Medical Sciences
Street address
Research Development Deputy, Ahvaz Jundishapour University of Medical Sciences, Golestan, Ahvaz
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61357-15794
Approval date
2015-07-25, 1394/05/03
Ethics committee reference number
IR.AJUMS.REC.1394.250

Health conditions studied

1

Description of health condition studied
Multiple sclerosis
ICD-10 code
G35
ICD-10 code description
Demyelinating diseases of the central nervous system

Primary outcomes

1

Description
Urinary disorder
Timepoint
Before intervention and one month after intervention
Method of measurement
Incontinence Quality of Life Questionnaire (I-QOL)

Secondary outcomes

1

Description
side effect
Timepoint
During intervention
Method of measurement
Incontinence Quality of Life Questionnaire (I--QOL)

Intervention groups

1

Description
Frankincense,300 mg capsule ,oral,bid for one month
Category
Treatment - Drugs

2

Description
placebo cpasule,starch and sugar,bid for one month
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Khouzestan MS Association
Full name of responsible person
Mrs Nedamat

Street address
School of Rehabilitation, Golestan Hospital, Ahwaz
City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Mr Dianat
Street address
Research Development Deputy, Ahvaz Jundishapur University of Medical Sciences, Golestan, 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 Jundishapur 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

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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