

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 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

Name

Alireza Omidinia

Name of organization / entity

Ahwaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8835 1571

Email address

omidinia.a@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahwaz 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

City

Ahvaz

Postal code

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 capsule, starch and sugar, bid for one month

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Khuzestan MS Association

Full name of responsible person

Mrs Nedamat

Street address

School of Rehabilitation, Golestan Hospital, Ahvaz

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

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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

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**Contact****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Alireza Omidinia

Position

pharmacy student

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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