

# 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**

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

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Alireza Omidinia

**Position**

pharmacy student

**Other areas of specialty/work****Street address**

School of Pharmacy, Ahvaz Jundishapur University of Medical Sciences, Golestan, Ahvaz

**City**

Ahvaz

**Postal code****Phone**

+98 21 8835 1571

**Fax****Email**

omidiniaa@gmail.com omidinia.a@ajums.ac.ir

omidiniaa@yahoo.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Alireza Omidinia

**Position**

pharmacy student

**Other areas of specialty/work****Street address**

School of Pharmacy, Ahvaz Jundishapur University of Medical Sciences, Golestan, Ahvaz

**City**

Ahvaz

**Postal code****Phone**

+98 21 8835 1571

**Fax****Email**

omidiniaa@gmail.com omidinia.a@ajums.ac.ir

omidiniaa@yahoo.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Alireza Omidinia

**Position**

pharmacy student

**Other areas of specialty/work****Street address**

School of Pharmacy, Ahvaz Jundishapur University of Medical Sciences, Golestan, Ahvaz

**City**

Ahvaz

**Postal code****Phone**

+98 21 8835 1571

**Fax****Email**

omidiniaa@gmail.com omidiniaa@ajums.ac.ir

omidiniaa@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*