# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

19 Sep 2026

## Effect of MS14, an herbal marine drug on physical activity improvement in patients with multiple sclerosis; a double blind, placebo controlled study

## Protocol summary


**Study aim**

Assessment of natural product, MS14 effect on movement disorder improvement of patients with multiple sclerosis

**Design**

In this study, 100 patients with multiple sclerosis who fulfill the inclusion criteria of the study are entered the trial. They are divided in two groups randomly; MS14 and placebo. To blind the participants, they receive special codes.

**Settings and conduct**

The study is performed in Iranian Center of Neurological Research in Tehran University of Medical Sciences. MS14 and placebo get a specific code. They are similar in face. Patients and physicians who assess the clinical symptoms, are not aware about the content of each sample.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: Patients whose symptoms fulfill MS diagnosis criteria; Minimum age of 18 years old; Problems in walking, Ability to walk more than 5 meters with or without help, Stability of disease condition during past 6 months. Exclusion criteria: Using other drugs effective in movement; Using other natural remedies; Cardiovascular diseases; Pregnancy, Disease relapse during the trial, Having active and known infection, Like to use another new drug effective on patient's symptoms, Major cognitive disorder or psychotic disease, Advanced movement disorder like fixed tendon contracture, Abnormality in blood test in beginning of the study, Major depression.

**Intervention groups**

In this study, participants will be divided into placebo and MS14 (drug) groups. Each group will receive MS14 or placebo 50 milligrams for 1 kilogram of body weight. Clinical symptoms will be assessed before and 3 weeks after the intervention.

**Main outcome variables**

Job related activities, walking distance during the day, transportation; physical activity, moderate physical activity and general physical activity according to international physical activity questionnaire will be assessed.


## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20161203031205N3**
Registration date: **2018-04-18, 1397/01/29**
Registration timing: **registered_while_recruiting**

Last update: **2018-04-18, 1397/01/29**
Update count: **0**

**Registration date**

2018-04-18, 1397/01/29

**Registrant information**


**Name**

Mohsen Naseri

**Name of organization / entity**

Traditional Iranian Medicine Clinical Trial Research

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 2288 2596

**Email address**

r.jafari.hajati@gmail.com


**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2018-02-04, 1396/11/15

**Expected recruitment end date**
2020-02-04, 1398/11/15
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Effect of MS14, an herbal marine drug on physical activity improvement in patients with multiple sclerosis; a double blind, placebo controlled study

**Public title**
Effect of MS14 on multiple sclerosis
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Fulfill MS diagnosis criteria Minimum age of 18 years Problems in walking Ability to walk more than 5 meters with or without helping Disease condition should be stable during past 6 months
**Exclusion criteria:**
Cardiovascular diseases Pregnancy Disease relapse during the trial Having active and known infection Like to use another new drug effective on patient's syptoms Major cognitive disorder or psychotic disease Advanced movement disorder like fixed tendon contracture Abnormality in blood test in beginning of the study Major depression Using other drugs effective in movement Using other natural remedies
**Age**
From **18 years** old
**Gender**
Both

**Phase**
2-3
**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**
Target sample size: **100**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
In this study, we divide patients into drug and control groups by randomization. according to the number of patients in each group, Drug and placebo are coded using random numbers by biostatistics group and then are given to related physicians.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
All of the participants and also physicians who give the placebo or drug to the patients and assess the clinical symptoms before and after the intervention, are unaware about the content of samples. MS14 and placebo samples have similar appearances. There are codes on the package of samples and only the statistics analyst is aware of content of each code. The physician give the sample to the patients, while he does not know the content of each code.
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Shahed University
**Street address**
Shahed University, Tehran Qom Freeway
**City**
Tehran
**Province**
Tehran
**Postal code**
1417953836
**Approval date**
2008-02-24, 1386/12/05
**Ethics committee reference number**
shahed.REC.1386.6

## 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**
Transportation physical activity
**Timepoint**
Before and 3 weeks after intervention
**Method of measurement**
International physical activity questionnaire

### 2

**Description**
moderate physical activity
**Timepoint**
Before and 3 weeks after intervention

**Method of measurement**
International physical activity questionnaire

**3**

**Description**
Total physical activity index
**Timepoint**
Before and 3 weeks after intervention
**Method of measurement**
International physical activity questionnaire

## Secondary outcomes

**1**

**Description**
Fatigue severity
**Timepoint**
Before and 3 weeks after the intervention
**Method of measurement**
Fatigue severity scale

**2**

**Description**
Timed 10 meter walk
**Timepoint**
Before and 3 weeks after intervention
**Method of measurement**
measuring the time needed for 10 meter walk

**3**

**Description**
spasticity severity
**Timepoint**
Before and 3 weeks after the intervention
**Method of measurement**
Ashworth scale

**4**

**Description**
Timed get up and go
**Timepoint**
Before and 3 weeks after intervention
**Method of measurement**
measuring the time needed from getting up until initiating the activity

## Intervention groups

**1**

**Description**
Intervention group: They will recieve MS14, 50 milligram for each kilogram of body weight daily in the form of caplet for 3 weeks. MS14, a natural product will be made mainly from Penaeus latisculatus, Apium graveolense L. and Hypericum perforatum L. in Herbal Medicine Research Center of Shahed University.
**Category**
Treatment - Other

**2**

**Description**
Control group: Control group will recieve starch caplet, 50 milligram for each kilogram of body weight for 3 weeks.
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Iranian Center of Neurological Research in Tehran University of Medical Sciences
**Full name of responsible person**
Mohsen Naseri
**Street address**
Imam Khomeini Hospital, East Bagherkhan Street, Chamran Highway
**City**
Tehran
**Province**
Tehran
**Postal code**
1419733141
**Phone**
+98 21 6646 4320
**Email**
naserishahed1395@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Shahed University
**Full name of responsible person**
Zahra Kiasalari Rineh
**Street address**
Tehran Qom Freeway, Tehran
**City**
Tehran
**Province**
Tehran
**Postal code**
3319118651
**Phone**
+98 21 5527 7400
**Email**
kiasalari@shahed.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes

**Title of funding source**
Shahed University
**Proportion provided by this source**
100
**Public or private sector**
Public
**Domestic or foreign origin**
Domestic
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
Academic

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Shahed University
**Full name of responsible person**
Mohsen Naseri
**Position**
Associate professor
**Latest degree**
Specialist
**Other areas of specialty/work**
pharmacology
**Street address**
No. 1471, North Karegar Ave, Enghelab square
**City**
Tehran
**Province**
Tehran
**Postal code**
1314666144
**Phone**
+98 21 6646 4420
**Email**
naserishahed1395@gmail.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Shahed University
**Full name of responsible person**
Mohsen Naseri
**Position**
Associate professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Pharmacology
**Street address**
No. 1471, North Karegar Ave, Enghelab square
**City**
Tehran
**Province**
Tehran
**Postal code**
1314666144
**Phone**
+98 21 6646 4320
**Email**
naserishahed1395@gmail.com

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Shahed University
**Full name of responsible person**
Mohsen Naseri
**Position**
Associate professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Pharmacology
**Street address**
No. 1471, North Karegar Ave, Enghelab Square
**City**
Tehran
**Province**
Tehran
**Postal code**
1314666144
**Phone**
+98 21 6646 4320
**Email**
naserishahed1395@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available
**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available
**Statistical Analysis Plan**
No - There is not a plan to make this available
**Informed Consent Form**
No - There is not a plan to make this available
**Clinical Study Report**
Undecided - It is not yet known if there will be a plan to make this available
**Analytic Code**
No - There is not a plan to make this available
**Data Dictionary**
No - There is not a plan to make this available