

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 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 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 receive 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 latissculatus*, *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 receive 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