Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The study of the effectivness of iranian lavender on tremor of Multipl Sclerosis patients: (Randomized controlled trial)

Protocol summary

Summary

The purpose of the study: Compare the intensity of the tremor in multiple sclerosis patients receiving Iranian Laveder with placebo. Study design: Randomized, double-blind, placebo-controlled, single-center, phase two trials. The method of study: - Study population:Proven MS patients in the age range 15 to 50 years registered in the Khuzestan MS Community without no Allergy to lavender and any other serious and chronic disease(exeption MS), and no pregnancy or breastfeeding in women. -Sample size:Due to lack of proper estimation of the possible effect of the drug on the results of previous similar studies,the sample size will be determined based on the results of a pilot study. - Intervention study:The study was a randomized controlled clinical trial, patients are devided randomized in to two groups, receiving Lavender or placebo (both medication form and taste are simillar).Each group receives placebo or medication for eight(8) weeks.Immediately before the intervention and after the end of the eighth week,Patients will be evaluated in terms of changes in tremor severity with two types of questionnaire(The tremor part of the MDS-UPDRS questionnaire) and also by the tremor detector (Motion Capture System). -Intervention time:8(eight) weeks -The primary outcome of the study:Finally, by comparing the changes as well as changes in questionnaire and tremor amplitude that would be reported by Motion Capture System (Analysis is based on the tremor research group scale), we will be judged on the effectiveness of the drug and placebo.

General information

Acronym

MS: Multiple Sclerosis MDS-UDPRS: Movement Disorder Society-Unified Parkinson’s Disease Rating Scal

IRCT registration information

IRCT registration number: **IRCT2016082429511N1**

Registration date: **2016-09-17, 1395/06/27**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-09-17, 1395/06/27

Registrant information

Name

Golakeh Karimi

Name of organization / entity

Ahvaz Jundishapur Univercity of Medical Siences

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3012

Email address

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundi Shapur University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study of the effectivness of iranian lavender on tremor of Multipl Sclerosis patients: (Randomized controlled trial)

Public title
The effect of Lavender planet in the treatment on tremor of Multipl Sclerosis patients.
Purpose
Treatment
Inclusion/Exclusion criteria
Including criteria: 1:Having proven MS according to the clinical examination and medical history 2:EDSS rating between 2 to 5.5 3:Having constant and regular medical treatment in the past 4 weeks 4:Consent to use of alternative medicines 7 days before the start of intervention to the end of intervention 5:Not be in another study at the same time 6:Age 15 to 50 years Excluding criteria: 1:History of alcohol or drug dependence 2:pregnancy or Breastfeeding 3:Impaired renal and/or liver function 4:Treatment with steroids over a month before the start of the study 5:Having a neurological disease in addition to multiple sclerosis 6: Having Cardiovascular or Lung disease(such as Asthma) or Diabetes 7:Allergy to Lavender
Age
From **15 years** old to **50 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size:
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Blocked randomization

Secondary Ids

1

Registry name
_
Secondary trial Id
_
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jundishapur Univercity of Medical Siences
Street address
Ahvaz jundishapur Univercity of Medical Siences,Golestan quarter,Ahvaz
City
Ahvaz
Postal code
Approval date
2016-04-28, 1395/02/09
Ethics committee reference number
IR.AJUMS.REC.1395.50

Health conditions studied

1

Description of health condition studied
Multiple Sclerosis
ICD-10 code
G00-G99
ICD-10 code description
G35

Primary outcomes

1

Description
Tremor
Timepoint
Questionnair :before the intervention, after four weeks of intervention and after the intervention / Tremor measuring machine: before the intervention and after the intervention
Method of measurement
Questionnair:Tremor part from MDS-UDPRS/ Tremor measuring machine(Motion Capture System)

Secondary outcomes

1

Description
Drug Side effects
Timepoint
Four weeks after the intervention, after intervention
Method of measurement
Oral questions from patients

Intervention groups

1

Description
Control group: placebo, oral capsule, Once a day for 8 weeks, made by Barijessence Pharmaceutical Factory
Category
Placebo

2

Description
Intervention group: Iranian Lavender oil, 80 mg oral capsule, Once a day for 8 weeks, made by Barijessence Pharmaceutical Factory
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Golestan Hospital
Full name of responsible person
Golakeh Karimi, Neurology Resident, Medical Student
Street address
Golestan Hospital, Golestan quarter, Golestan Hospital
City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Reasearch center of Ahvaz Jundishapur Univercity of Medical Siences
Full name of responsible person
Behzad Sharif Makhmal Zade
Street address
Vice Reasearch office, Ahvaz Jundishapur Univercity of Medical Siences, Golestan quarter, Ahvaz
City
Ahvaz
Grant name
_
Grant code / Reference number
_
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Reasearch center of Ahvaz Jundishapur Univercity of Medical Siences
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 Univercity of Medical Miences
Full name of responsible person
Golakeh Karimi
Position
General practitioner/ Neurology Resident
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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