Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effectiveness of lavender capsules (linazepam) with placebo in improving depression symptoms in patients with multiple sclerosis

Protocol summary

Study aim

Evaluation of the efficacy of the lavender on improving the symptoms of depression of patients with multiple sclrosis

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, on 60 patients. NCSS (Number Cruncher statistical system) software and block random method are used to randomize the study

Settings and conduct

Sixty patients who have been diagnosed with multiple sclerosis and referred to the Imam Rezai Clinic in Shiraz in 2023 will be enrolled in the study. These patients will be randomly allocated to either the placebo group or the lavender (linazepam) group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Men and women aged between 18-50 years with relapsing-remitting multiple sclerosis who score above 11 on the Persian version of the Beck Depression Inventory-II (BDI-II-Persian). Exclusion criteria: Pregnancy and lactation Allergy to N. menthoides and Asteraceae family Patients with unstable cardiac, renal, and hepatic diseases, seizure and hypothyroidism, and substance or alcohol abuse Patients who will be lost to follow-up Patients with severe depression.

Intervention groups

Intrvention group: patients receive 50 to 100mg of sertraline daily with a linazpam(lavender) capsule. Placebo group: patients receive 50 to 100mg of sertraline daily with one placebo capsule.

Main outcome variables

Change in score of Beck Depression Inventory-II (BID-II-Persian)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190726044339N4**
Registration date: **2023-03-03, 1401/12/12**
Registration timing: **registered_while_recruiting**

Last update: **2023-03-03, 1401/12/12**
Update count: **0**

Registration date

2023-03-03, 1401/12/12

Registrant information

Name

Seyed Hamdollah Mosavat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3725 4105

Email address

hamdi_88114@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-07-23, 1402/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effectiveness of lavender capsules (linazepam) with placebo in improving depression symptoms in patients with multiple sclerosis

Public title
Investigating the effect of lavender on depression in patients with multiple sclerosis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Men and women with Relapsing-remitting multiple sclerosis patients with aged between ۱۸-۵۰ years Score above ۱۱ according to Persian- version of the Beck Depression Inventory-II (BDI-II-Persian)

Exclusion criteria:
Pregnancy and breastfeeding Allergy to lavender Unstable heart, kidney and liver patients Seizures Hypothyroidism Consumption of alcohol or drugs Patients who do not follow the study completely Patients with severe depression

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The researcher enrolls participants based on the convenience sampling method. NCSS software (Number Cruncher Statistical System) and block randomization are used for randomizing the study. In the block randomization method, participants are categorized into 6 blocks (AABB, ABAB, BBAA, BABA, ABBA, BAAB), with each block containing 4 participants. In this study, "A" is assigned to the drug group and "B" to the placebo group. For example, in the "ABAB" block, the first person enters the drug group, the second person enters the placebo group, the third person enters the drug group, and the fourth person enters the placebo group. Thus, all eligible participants are randomly assigned to one of the study arms according to the randomization list.

Blinding (investigator's opinion)
Double blinded

Blinding description
Physicians, patients, and drug deliverer will blind to the allocation of intervention. It should be noted that the drugs' containers is the same. Additionally, placebo capsule is similar to lavender capsule regarding the color and shape

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University of Medical Sciences

Street address
Namazi Square, Imam Reza Clinicl

City
Shiraz

Province
Fars

Postal code
7134845794

Approval date
2022-08-27, 1401/06/05

Ethics committee reference number
IR.SUMS.MED.REC.1401.253

Health conditions studied

1

Description of health condition studied
Multiple Sclerosis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Change in Beck questionnaire score

Timepoint
Measurement of depression severity at the beginning of the study (before the start of the intervention) and 4, 8 weeks after the start of taking the drug or placebo.

Method of measurement
Depression Beck questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: Participants in this group will be prescribed one capsule of linazepam, which contains lavender essence, one hour before bedtime for eight weeks at night. This linazepam capsule is a pharmaceutical product available in the market and was purchased from Arum Teb Daro Pharmaceutical Company. Additionally, patients in this group will receive routine treatment for depression, which includes one tablet of sertraline (Abidi-Tehran Pharmaceutical Company, Tehran, Iran) 100 mg per day.

Category

Treatment - Drugs

2

Description

Control group: Participants in this group will be prescribed one placebo capsule one hour before bedtime for eight weeks at night.The placebo capsule is made by the co-pharmacist of the project at the Faculty of Pharmacy of Shiraz University of Medical Sciences.Also, patients in this group receive routine treatment for depression (one sertraline tablet 100 mg per day).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Clinic
Full name of responsible person
Sara Dehbzorgi
Street address
Namazi square
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences
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Grant name

Mohammad Hashem Hashempur

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz University of Medical Sciences

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
Shiraz University of Medical Sciences
Full name of responsible person
Sara Dehbozorgi
Position
Assistant professor
Latest degree
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Person responsible for updating data

Contact

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Position
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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
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available