

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the effect of *Lavandula Angustifolia*, *Echium amoenum*, and *Melissa officinalis* in comparison with sertraline in the treatment of mild to moderate depression in older adults: A triple-blind randomized controlled trial

Protocol summary

Study aim

Determining the effect of Lavander, *Echium amoenum*, and *Melissa* in comparison with sertraline in the treatment of mild to moderate depression in older adults

Design

A triple-blind randomized clinical trial with four groups: *Lavandula* and *Melissa*, *Melissa* and *Echium amoenum*, *Lavandula* and *Echium amoenum*, and sertraline.

Settings and conduct

Patients will be randomly divided into four groups: *Lavandula* and *Melissa*, *Melissa* and *Echium amoenum*, *Lavandula* and *Echium amoenum*, and sertraline. The study is triple-blind (researchers, participants, and outcome evaluators will not be aware of the groups involved).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 60 years, mild to moderate depression (depression score of 18 to 24 in the Hamilton questionnaire). Exclusion criteria: no use of antidepressants and antipsychotics and mood-stabilizing nutrients four weeks before the clinical trial, suicidal ideation, symptoms of major depression, alcohol use in the past 12 months, warfarin and phenytoin, people who have just started psychotherapy, Pregnancy, and lactation, taking birth control pills, substance abuse, head trauma, hypothyroidism, and dementia, bipolar spectrum, psychoses, receiving ECT

Intervention groups

Lavandula and *Melissa* group will receive 1 capsule 250mg *Lavandula* (1g) and *Melissa* (1g), *Melissa* and *Echium amoenum* group will receive 1 capsule 250mg *Melissa* (1g) and *Echium amoenum* (500mg), *Lavandula* and *Echium amoenum* group will receive 1 capsule 250mg *Lavandula* (1g) and *Echium amoenum* (500mg), and sertraline group will receive 1 capsule 250mg containing 12.5 mg sertraline for first 10 days and 50 mg

in next 46 days, every 12 hours for 8 weeks.

Main outcome variables

The rate of depression measured by the Hamilton Questionnaire in the first, second, fourth, and eighth weeks.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140617018126N5**

Registration date: **2021-06-04, 1400/03/14**

Registration timing: **prospective**

Last update: **2021-06-04, 1400/03/14**

Update count: **0**

Registration date

2021-06-04, 1400/03/14

Registrant information

Name

Mostafa Araj-Khodaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2022-04-21, 1401/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Lavandula Angustifolia, Echium amoenum, and Melissa officinalis in comparison with sertraline in the treatment of mild to moderate depression in older adults: A triple-blind randomized controlled trial

Public title

The effect of Lavandula Angustifolia, Echium amoenum, and Melissa officinalis in comparison with sertraline in the treatment of mild to moderate depression in older adults

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 60 years People referring to a psychiatrist with mild to moderate depression who have a depression score of 18 to 24 in the Hamilton questionnaire

Exclusion criteria:

No use of antidepressants and antipsychotics and mood-stabilizing nutrients four weeks before the clinical trial Having suicidal ideation Symptoms of major depression Alcohol use in the past 12 months Warfarin and phenytoin use People who have just started psychotherapy People who are pregnant and lactation Taking birth control pills Substance abuse Biological and physical factors such as head trauma, hypothyroidism, dementia, bipolar spectrum, and psychoses Receiving ECT

Age

From **60 years** old to **100 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be randomly assigned to 8 blocks using Random Allocation Software. Blocking and allocation sequences for concealment will be done by the non-involved researcher (Allocation Concealment). The sample allocation ratio will be Allocation 1:1 and will be divided into 4 groups of Lavandula Angustifolia and Melissa officinalis, Melissa Officinalis and Echium

amoenum, Lavandula Angustifolia and Echium amoenum, and finally sertraline. In the next step, each client will receive white envelopes that are prepared in equal sizes and on which group .. drugs (for the first 10 days of study) and group ... drugs (for the next 46 days) are written. Also, each envelope will be numbered from 1 to 120 (in the order to allocation sequence). Groups ... and ... will have different contents only in the group of patients who will receive sertraline so that group .. contains 12.5 mg sertraline and group ... contains 50 mg of sertraline. Only the person in charge of packing drugs will know the numbers of the relevant pockets and none of the researchers or patients will know the type of medicine that each person receives. The first person will be given pocket number 1 and then it will continue until completion. Lavandula Angustifolia and Melissa officinalis, Melissa Officinalis and Echium amoenum, Lavandula Angustifolia and Echium amoenum, and sertraline capsules will be similar in shape, size, color and, smell.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Based on blocks and allocation sequences each client will be given white pockets that are prepared in equal sizes and on which the numbers 1 to 120 are written (in order of allocation sequence). The pockets will contain white boxes containing Lavandula Angustifolia and Melissa officinalis, Melissa Officinalis and Echium amoenum, Lavandula Angustifolia and Echium amoenum, and sertraline capsules. Only the person in charge of packing Lavandula Angustifolia and Melissa officinalis, Melissa Officinalis and Echium amoenum, Lavandula Angustifolia and Echium amoenum, and sertraline capsules will know the numbers of the relevant pockets and none of the researchers, patients, or outcome evaluators will know the type of medicine that each person receives. The first person will be given pocket number 1 and then it will continue until completion. All capsules will be similar in shape, size, color, and smell.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

Research Vice Chancellor, Third Floor, Central Building No. 2, Tabriz University of Medical Sciences, Golgasht Street, Tabriz

City

Tabriz

Province

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Postal code

5166614766

Approval date

2021-04-26, 1400/02/06

Ethics committee reference number

IR.TBZMED.REC.1400.090

Health conditions studied**1****Description of health condition studied**

Depression

ICD-10 code

F32.8

ICD-10 code description

Other depressive episodes

Primary outcomes**1****Description**

Depression

Timepoint

The first, second, fourth and eighth weeks

Method of measurement

Hamilton Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: This group will receive one capsule 250mg containing a combination of Lavandula Angustifolia (1 g) and Melissa officinalis (1 g) every 12 hours for two months. The capsules will be provided by Andisheh Tebe Boali Company.

Category

Treatment - Drugs

2**Description**

Intervention group: This group will receive one capsule 250 mg containing a combination of Melissa Officinalis (1 g) and Echium amoenum (500mg), every 12 hours for two months. The capsules will be provided by Andisheh Tebe Boali Company.

Category

Treatment - Drugs

3**Description**

Intervention group: This group will receive one capsule of 250mg containing a combination of Lavandula Angustifolia (1 g) and Echium amoenum (500 mg) every 12 hours for two months. The capsules will be provided by Andisheh Tebe Boali Company.

Category

Treatment - Drugs

4**Description**

Control group: The group will first receive one capsule 250 mg containing (12.5 mg) of sertraline for first 10 days and then one capsule (50 mg) of sertraline for the next 46 days every 12 hours and for 2 months.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Razi Hospital

Full name of responsible person

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2**Recruitment center****Name of recruitment center**

Baharan traditional medicine

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Mostafa Araj-Khodaei

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not 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

No - There is not 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