Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 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

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Name of organization / entity

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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 to120 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
East Azarbaijan
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
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Sponsors / Funding sources

1

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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
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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