Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Evaluation of the effect of Lavandula angustifolia and Melissa officinalis products using nasal spray method on mild to moderate depression

Protocol summary

Study aim
Determining the effect of Lavandula angustifolia and Melissa officinalis products using nasal spray method on mild to moderate depression

Design
A double-blind randomized clinical trial with four groups: Melissa Officinalis, Lavandula angustifolia, combination of Melissa Officinalis and Lavandula angustifolia and placebo (Pilot Study)

Settings and conduct
The study will be conducted at Razi Hospital Clinic as a pilot study. Patients will be randomly divided into four groups of Melissa Officinalis, Lavandula angustifolia, combination of Melissa Officinalis and Lavandula angustifolia , and placebo by block method. The researchers and participants will not be aware of the groups involved).

Participants/Inclusion and exclusion criteria
Having mild to moderate depression, Age 18-60 years, History or other psychiatric illness, History of allergy to herbal medicines, Taking psychiatric or herbal medicines during the last 2 weeks, Having severe or chronic medical diseases, Pregnant and lactating women, History of suicide attempts, Having hypothyroidism and high blood pressure

Intervention groups
The Melissa Officinalis recipient will recieve nasal spray containing one percent (one gram per hundred cc) of Melissa Officinalis. The Lavandula angustifolia recipient will recieve nasal spray containing one percent (one gram per hundred cc) of Lavandula angustifolia. The combination of Melissa Officinalis and Lavandula angustifolia recipient will recieve nasal spray containing one percent (one gram per hundred cc) of combination of Melissa Officinalis and Lavandula angustifolia. The placebo recipient will recieve nasal spray containing one percent water (one gram per hundred cc) of placebo.

Main outcome variables
The level of depression will be checked by a psychiatrist and Hamilton's depression questionnaire.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140617018126N7**
Registration date: **2022-11-02, 1401/08/11**
Registration timing: **prospective**

Last update: **2022-11-02, 1401/08/11**
Update count: **0**

Registration date
2022-11-02, 1401/08/11

Registrant information

Name
Mostafa Araj-Khodaei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3337 9528

Email address
araj@tbzmed.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-21, 1401/11/01

Expected recruitment end date
2023-09-22, 1402/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation of the effect of Lavandula angustifolia and Melissa officinalis products using nasal spray method on mild to moderate depression

Public title
The effect of Lavandula angustifolia and Melissa officinalis on depression

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having mild to moderate depression Age 18-60 years

Exclusion criteria:
History or other psychiatric illness History of allergy to herbal medicines Taking psychiatric or herbal medicines during the last 2 weeks Having severe or chronic medical diseases Pregnant and lactating women History of suicide attempts Having hypothyroidism and high blood pressure

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization sequences will be done using the random block method with ten blocks, and the intended interventions for each of the four studied groups will be determined in the form of ten-digit codes, through which it will not be possible to recognize the intervention by patients and researchers, and in other words, it will be done double-blind. The sample allocation ratio will be Allocation 1:1 and will be divided into two groups of receiving Melissa officinalis, Lavandula angustifolia, combination of Melissa officinalis and Lavandula angustifolia, and placebo (Assignment). Blocking and allocation sequences for concealment will be done by the non-involved researcher (Allocation Concealment). It is worth mentioning that the appearance and smell of all four interventions will be such that it will not be possible to distinguish each one from the other.

Blinding (investigator's opinion)
Double blinded

Blinding description
The intended interventions for each of the four groups will be determined in the form of ten-digit codes. Based on the obtained codes, each client will be given white pockets that are prepared in equal sizes and on which the numbers 1 to 80 written on them (according to the order of allocation). The pockets will contain white boxes containing lemongrass spray, lavender, a combination of Melissa officinalis, Lavandula angustifolia, combination of Melissa officinalis and Lavandula angustifolia, and placebo. Only the person in charge of packing will know the numbers of the respective envelopes, and none of the researchers or patients will know the type of intervention that each person receives. The first person will be given pocket number 1 and then it will continue until completion. It is worth mentioning that the appearance and smell of all four interventions will be such that it will not be possible to distinguish each one from the other.

Placebo
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
2022-10-10, 1401/07/18

Ethics committee reference number
IR.TBZMED.REC.1401.619

Health conditions studied

1

Description of health condition studied
Depression

ICD-10 code
F32.1

ICD-10 code description
Major depressive disorder, single episode, moderate

Primary outcomes

1

Description
The level of depression

Timepoint
Week 0, 3 and 6
Method of measurement
Visit by psychiatrist and Hamilton questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This group will receive Melissa Officinalis nasal spray containing one percent (one gram per hundred cc) of Melissa Officinalis. The sprays will be provided by Sina Noandish Tabiat Company.
Category
Treatment - Other

2

Description
Intervention group: This group will receive Lavandula angustifolia nasal spray containing one percent (one gram per hundred cc) of Lavandula angustifolia. The sprays will be provided by Sina Noandish Tabiat Company.
Category
Treatment - Other

3

Description
Intervention group: This group will receive the combination of Melissa Officinalis and Lavandula angustifolia nasal spray containing one percent (one gram per hundred cc) of each plant. The sprays will be provided by Sina Noandish Tabiat Company.
Category
Treatment - Other

4

Description
Control group: This group will receive a placebo spray containing the water. The sprays will be provided by Sina Noandish Tabiat Company.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Hospital Clinic
Full name of responsible person
Seyed Mostafa Araj khodaie
Street address
El Goli, next to Shohada Medical Training Center, Razi Hospital
City
Tabriz
Province
East Azarbaijan
Postal code
5166614756
Phone
+98 41 3334 2178
Email
araj@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Parviz Shahbi
Street address
Third Floor, Central Building No. 2, Tabriz University of Medical Sciences, Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Phone
+98 41 3335 7310
Email
research-vice@tbzmed.ac.ir
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
Seyed Mostafa Araj khodaie
Position
Assistant Professor

Latest degree
Ph.D.
Other areas of specialty/work
Traditional Medicine
Street address
Aging Research Institute, Faculty of medicine, Tabriz University of Medical Sciences, Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Phone
+98 41 3334 2178
Email
araj@tbzmed.ac.ir

Person responsible for scientific 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
Street address
Aging Research Institute, Faculty of medicine, Tabriz University of Medical Sciences, Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Phone
+98 41 3334 2178
Email
araj@tbzmed.ac.ir

Person responsible for updating data

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
Street address
Aging Research Institute, Faculty of medicine, Tabriz University of Medical Sciences, Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Phone
+98 41 3334 2178
Email
araj@tbzmed.ac.ir

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