

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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 receive nasal spray containing one percent (one gram per hundred cc) of *Melissa Officinalis*. The *Lavandula angustifolia* recipient will receive nasal spray containing one percent (one gram per hundred cc) of *Lavandula angustifolia*. The combination of *Melissa Officinalis* and *Lavandula angustifolia* recipient will receive nasal spray containing one percent (one gram per hundred cc) of combination of *Melissa Officinalis* and *Lavandula angustifolia*. The placebo recipient will receive 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)

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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

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahbi

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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

Seyed Mostafa Araj khodaie

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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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