

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Effect of *Melissa officinallis* and *Lavandula angustifolia* products in treatment of depression.

Protocol summary

Shahed University, Vice Chancellor for Research

Summary

The aim of this randomized double blind study is comparison of antidepressant effect of *Melissa officinallis* and *Lavandula angustifolia* with fluoxetine. A total of sixty patients with major depressive disorder (mild to moderate) referring to psychiatry clinics are recruited and randomly assigned to receive either 20 mg of fluoxetine or 2 gr of *Melissa officinallis* and 2 gr of *Lavandula angustifolia* for 8 weeks. Severity of depression is assessed by the Hamilton Depression Rating Scale in weeks 0, 2, 4, and 8 after intervention.

Expected recruitment start date

2015-05-23, 1394/03/02

Expected recruitment end date

2015-10-24, 1394/08/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of *Melissa officinallis* and *Lavandula angustifolia* products in treatment of depression.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014061718126N1**

Registration date: **2015-06-04, 1394/03/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-06-04, 1394/03/14

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

Public title

Effect of *Melissa Officinalis* and *lavandula angustifolia* in treatment of depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 18 - 65 years old; DSM-V criteria for major depressive disorder (mild to moderate); signed informed consent. Exclusion criteria: positive history of other psychological disorders; consumption of alcohol or other addictive substances in last 2 weeks; serious medical disease; allergic reaction to medical herbs; positive history of suicidal attempt or suicidal intention; pregnancy; consumption of thyroid disorders drugs.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee for Medical Research, Shahed University

Street address

Shahed university-Opposite of Imam Khomeiny shrine-Qom freeway

City

Tehran

Postal code

Approval date

2015-03-15, 1393/12/24

Ethics committee reference number

41/226696

Health conditions studied

1

Description of health condition studied

Major depressive disorder

ICD-10 code

F32

ICD-10 code description

Depressive episode

Primary outcomes

1

Description

Severity of depression

Timepoint

Baseline, 2, 4 and 8 weeks after starting the medication

Method of measurement

Hamilton rating scale for depression

Secondary outcomes

1

Description

Side Effects

Timepoint

0-2-4-8 weeks

Method of measurement

Clinical interview and physical examination and checklist

Intervention groups

1

Description

Melissa officinalis(each cap 500 mg)Usage: 2 cap every 12 hours for 8 weeks

Category

Treatment - Other

2

Description

Fluoxetine : (each cap 5 mg) Usage: 2 cap every 12 hours for 8 weeks

Category

Treatment - Drugs

3

Description

Lavandula Angustifolia (each cap 500 mg)Usage: 2 cap every 12 hours for 8 weeks

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Psychiatry clinic

Full name of responsible person

Dr Ahmad Ali Noorbala

Street address

Unit 13- Building 280- Dolat

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Hasan Namdar

Street address

Shahed university-Opposite of Imam Khomeiny shrine-Qom freeway

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahed University

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Seyed Mostafa Araj Khodaei

Position

PhD student

Other areas of specialty/work

Street address

1471-between forsat and nosrat-North kargar-Engelab square

City

Tehran

Postal code

Phone

+98 21 6646 4320

Fax

+98 21 6646 4322

Email

mostafaa33@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Mohsen Naseri

Position

Associate Professor of Pharmacology

Other areas of specialty/work

Street address

1471-between forsat and nosrat-North kargar-Engelab square

City

Tehran

Postal code

Phone

+98 21 6646 4320

Fax

+98 21 6646 4322

Email

naseri@shahed.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Seyed Mostafa Araj Khodaei

Position

PhD student

Other areas of specialty/work

Street address

1471-between forsat and nosrat-North kargar-Engelab square

City

Tehran

Postal code

Phone

+98 21 6646 4320

Fax

Email

m.aaraj@shahed.ac.ir; mostafaa33@gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty