Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Nov 2026

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

Protocol summary

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.

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

Shahed University, Vice Chancellor for Research

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.

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
Fluoxetin : (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

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Person responsible for scientific inquiries

Contact

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Mohsen Naseri

Position

Associate Professor of Pharmacology

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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