Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The comparison of the efficacy of hydroalcoholic extract of Ocimum basilicum and placebo in treatment of anxiety in depressed patients: A randomized double-blind clinical trial

Protocol summary

Study aim

Investigating the effectiveness of Ocimum basilicum hydroalcoholic extract on anxiety in patients with depression

Design

A clinical trial with a control group, with parallel groups, randomized double-blind, phase 2 and 3 on 60 patients, RAND function in Excel software is used for randomization.

Settings and conduct

Among the patients who referred to Dasghib Psychiatry Clinic (under Fasa University of Medical Sciences) randomly, 60 people who have major depression and also have anxiety problems, if they meet the conditions, after receiving written informed consent, were included in the study. At the beginning of the study, each patient completes 2 questionnaires, including Beck's Depression Severity Questionnaire and Hamilton's Anxiety Severity Index. Both groups will also be given standard medications for treating depression. The intervention group consumes a tablespoon of Ocimum basilicum hydroalcoholic extract every night, and the control group consumes a placebo with a similar appearance. The shape and packaging of the syrups of both groups will be the same, so patients and researchers will not be able to distinguish the drug from the placebo. Patients take a tablespoon of the syrup every night before going to bed. 4 weeks after the start of the treatment, the patients will be visited again and the questionnaires will be completed again.

Participants/Inclusion and exclusion criteria

Entry conditions: People with depression between 18 and 65 years old who score at least 18 in the Hamilton Questionnaire. Non-entry: patients with internal diseases such as heart and lung failure, cancer, etc

Intervention groups

The intervention group will use Ocimum basilicum syrup along with anti-depressants. The control group takes a placebo along with antidepressants.

Main outcome variables

Severity of depression, severity of anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230318057752N1**
Registration date: **2023-04-11, 1402/01/22**
Registration timing: **prospective**

Last update: **2023-04-11, 1402/01/22**
Update count: **0**

Registration date

2023-04-11, 1402/01/22

Registrant information

Name

Kiarash Zare

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-24, 1402/02/04

Expected recruitment end date

2023-12-21, 1402/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the efficacy of hydroalcoholic extract of Ocimum basilicum and placebo in treatment of anxiety in depressed patients: A randomized double-blind clinical trial

Public title

Effect of Ocimum basilicum in anxiety

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Men and women between 18 and 65 years old People with major depressive disorder based on DSM 5 criteria Obtaining a minimum score of 18 in the Hamilton Anxiety Questionnaire Not taking any new anti-anxiety medication in the last 1 month Not suffering from significant internal diseases such as heart and lung failure, cancer, vascular disease, rheumatological disease, history of seizures and hypothyroidism, etc. Not using anticoagulant or anti-platelet drugs such as warfarin, heparin, aspirin, etc. No drug and alcohol addiction

Exclusion criteria:

Any allergy to Ocimum basilicum and its products Pregnancy or breastfeeding Hypersensitivity to specific serotonin re-uptake inhibitor drugs Patients who will not have proper follow-up

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization of participants is based on limited randomization, in which case the number of people in each group will be equal. For this purpose, we will remove 30 white balls and 30 black balls that represent each of the studied groups from the bag without replacement and write down their order. Then we put opaque and sealed envelopes containing black or white coded questionnaires into a box in the same order as the balls are removed. This box will be placed in the place where the researcher is visiting the patients participating in the study, and after the patient enters the study, the envelopes will be delivered to the patients in the same order of placement. After receiving the envelope, people will complete the questionnaires in another room. Medicines and placebos are placed in boxes with the same appearance and sealed in another room and are delivered to them according to the white or black code recorded in the patient's questionnaire. None of the people present in the study will be involved in the randomization and the type of medicine received by the patient. Each part of the study, such as randomization, observation of the color code of the questionnaires, and drug delivery, will be done by someone outside the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

After the visit of the patients by the psychiatrist, closed transparent envelopes containing the questionnaires will be given to the patients who wish to participate in the study. In another room, the patient will complete the questionnaires inside the envelopes, which have predetermined numbers. The colleague in the room gives the patient a box with the same code as the questionnaire, which contains medicine or placebo. With this method, the researchers will be unaware of the drug or placebo. Due to the similarity between the drug and the placebo, the patient will not know the difference between them. None of the people present in the study will be involved in the randomization and the type of medicine received by the patient.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Fasa University of Medical Sciences

Street address

Ibn Sina square, Fasa

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Province

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Postal code

7461686688

Approval date

2023-03-15, 1401/12/24

Ethics committee reference number

IR.FUMS.REC.1401.251

Health conditions studied

1

Description of health condition studied
Depression, anxiety
ICD-10 code
F32
ICD-10 code description
Major depressive disorder, single episode

Primary outcomes

1

Description
Depression score in Beck questionnaire
Timepoint
Before starting the study and 4 weeks after taking the drug
Method of measurement
Based on the Beck Depression Questionnaire

2

Description
Anxiety score in Hamilton questionnaire
Timepoint
Before starting the study and 4 weeks after taking the drug
Method of measurement
Based on Hamilton anxiety questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For four weeks, he consumes one tablespoon of Ocimum basilicum hydroalcoholic extract syrup at a dose of 220 mg/ml every night. This syrup will be produced by the order of Fasa University of Medical Sciences in the Faculty of Pharmacy of Shiraz University of Medical Sciences.
Category
Treatment - Drugs

2

Description
Control group: For four weeks, he consumes a tablespoon of placebo syrup every night, which has the same shape and packaging as Ocimum basilicum syrup. In order to prepare placebo simple syrup according to the American Pharmacopoeia, 85 grams of sugar is mixed with 100 ml of distilled water (similar to the base of medicinal syrup) and mixed slowly at a temperature of 100 degrees until it becomes uniform and with the help of permitted food coloring It should be the same color as medicinal syrup.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Fasa University of Medical Sciences, Dastghib Clinic
Full name of responsible person
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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
Fasa 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

Fasa University of Medical Sciences

Full name of responsible person

Kiarash Zare

Position

Expert

Latest degree

Bachelor

Other areas of specialty/work

Laboratory Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Demographic information and clinical trial results

When the data will become available and for how long

6 months after the publication of the article, it will be possible to access the data.

To whom data/document is available

Researchers in all universities of medical sciences

Under which criteria data/document could be used

The applicant should submit her request to the Vice-Chancellor of Research and Technology of Fasa University of Medical Sciences, and if this vice-chancellor and the ethics committee of this university agree, the data will be provided to applicant .

From where data/document is obtainable

Fasa University of Medical Sciences, Vice President of Research and Technology

What processes are involved for a request to access data/document

Approval of the Research and Technology Vice-Chancellor and Ethics Committee of Fasa University of Medical Sciences

Comments