

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

The comparison of the efficacy of hydroalcoholic extract of ocimum basilicum and placebo in treatment of insomnia in depressed patients who are referred to psychiatry clinic of Hafez hospital in Shiraz (a randomized double blind clinical trial)

Protocol summary

Study aim

To determine the insomnia severity and sleep quality of the depressed patients who are referred to psychiatry clinic of Hafez hospital in 2018 after taking the Ocimum basilicum hydroalcoholic extract based on Insomnia Severity Index (ISI) and Pittsburgh Sleep Quality Index (PSQI).

Design

Two arm parallel group controlled randomised trial with double blinded outcome assessment

Settings and conduct

Major depression is the most prevalent psychiatric disease. Insomnia is one of the symptoms which is contributable to risk of suicide and recurrence rate. In spite of many hypnotic drugs, many patients still suffer from insomnia and drug side effects. Iranian traditional medicine as a subgroups of Complementary and Alternative Medicine has discussed about sedative features of Ocimum basilicum as has been documented in some animal studies. The study will be performed in Hafez hospital psychiatry clinic of Shiraz University of Medical Sciences(SUMS) in Shiraz, Iran. The patients who fulfill study criterias will be divided in two 30 people groups randomly. They will answer 3 questionnaire that record their depression and insomnia severity and sleep quality. Then they will receive drug or placebo and after 1 month they will again answer the questionnaires. Drug and placebo have same appearance. All steps of random allocation and delivering the drug and gathering the questionnaires will be done by a coworker out of the study. So both the researchers and the participants will be blinded in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: people between 18 - 65 years old who are suffering from major depression and concomitant insomnia
Exclusion criteria: significant medical diseases;

pregnancy; addiction

Intervention groups

One of the groups receives Ocimum basilicum extract and the other one receives placebo

Main outcome variables

Insomnia severity; sleep quality; depression severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180603039967N1**

Registration date: **2018-11-04, 1397/08/13**

Registration timing: **registered_while_recruiting**

Last update: **2018-11-04, 1397/08/13**

Update count: **0**

Registration date

2018-11-04, 1397/08/13

Registrant information

Name

Mohammadreza Nazari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-31, 1397/08/09
Expected recruitment end date
 2018-12-30, 1397/10/09
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 insomnia in depressed patients who are referred to psychiatry clinic of Hafez hospital in Shiraz (a randomized double blind clinical trial)

Public title
 The effect of basil extract in insomnia .

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 The patients between 18 to 65 years old suffering from major depression Getting at least the score 12 out of 28 of the insomnia severity index questionnaire
Exclusion criteria:
 Taking any sedative medication in last month Suffering from significant medical diseases like cardiopulmonary failure, cancer, vascular disease, rheumatologic diseases, history of seizure, thyroid disease, ... Taking anticoagulant or antiplatelet medications like warfarin, aspirin ,... Opioid and alcohol addiction Pregnancy and lactation

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
 In order to equalize the number of the members of the groups, the restricted randomization and random allocation rule will be used . in random allocation rule , classically 2 different color balls in equal numbers will be throwed in a bag and the order of removal of the balls will be recorded . participants will get in two groups by the same order (Of course this process will be done by randomization softwares and the code 1 and code 2 will be recorded instead of colors.) .Because the patients visit the doctor in a few days of a week and also a few number of the patients will fill the including criteria , the

sampling needs several days to complete . so sampling would be done via simple intermittent method and it starts with adding the first patient and finishes when the number of patients achieves the study goal . 60 not transparent sealed envelopes with same external appearance will be prepared in two 30 people groups as indicator of the participants . Each envelope consists of questionnaires with the code1 or 2. Based on the order of random allocation achieved in previous step, the envelopes are placed in a box in the office. The researcher who is visiting the patients, gives them the envelopes based on the order .After receiving the envelopes, the patients will open the envelope and fill the questionnaire in a separate room. The drug and the placebo are in separate boxes with same appearance. Each patient receives a box based on the code of the questionnaires (code1 or code2). It should be noted that none of the researchers of this study are involved in random allocation and aware of the boxes that patients receive. All the steps, including random allocation, seeing the code of the questionnaire, and giving the drug to the patients is done by a coworker out of the study .

Blinding (investigator's opinion)
 Double blinded

Blinding description
 After the patient was visited by the physician, a not transparent and sealed envelope containing the questionnaire and the code 1 or 2 will be given to the patient . The patient will open the envelope in a separate room and will answer the questionnaires. Questionnaires have a specific code and it would be seen by a coworker in that room and a box with the same code which may contain drug or placebo would be delivered to the patient. None of the researchers are aware of the code of the envelopes and questionnaires. As a result researchers are not aware of the source of the medications the patients are receiving. Also the patients can not differentiate between placebo and the drug due to same appearance and taste. It should be noted that none of the researchers of this study would be involved in random allocation and aware of the boxes that patients receive. All the steps, including random allocation, seeing the code of the questionnaire, and giving the drug box to the patients is done by a coworker out of the study .

Placebo
 Used

Assignment
 Parallel

Other design features

Secondary Ids
 empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee of Shiraz University of Medical

Sciences

Street address

Shiraz University of Medical Sciences central building,
Zand Blvd

City

Shiraz

Province

Fars

Postal code

71345-1978

Approval date

2018-08-19, 1397/05/28

Ethics committee reference number

IR.SUMS.MED.REC.1397.228

Health conditions studied

1

Description of health condition studied

Major depression + Insomnia

ICD-10 code

G47.0

ICD-10 code description

Insomnia

Primary outcomes

1

Description

Beck depression inventory score /Insomnia Severity
Index score (ISI) / Pittsburgh Sleep Quality Index
score(PSQI)

Timepoint

Filling the questionnaires before starting the intervention
and 4 week after taking drug

Method of measurement

Beck depression inventory /Insomnia Severity Index (ISI)
/ Pittsburgh Sleep Quality Index (PSQI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Ocimum basilicum will be dried and
hydroalcoholic extract will be prepared. Capsules will be
filled with hydroalcoholic extract powder . The patients
will receive 1100 mg of extract 1 hour before sleep each
night. The patients will receive the capsules for 4 weeks.
The extract is made in school of pharmacy of SUMS.

Category

Treatment - Drugs

2

Description

Control group: Placebo with same appearance will be
prepared for control group. Capsules will be filled with
starch .

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Psychiatry clinic; Hafez hospital; SUMS

Full name of responsible person

Dr Amir Bazrafshan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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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

Shiraz 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
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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All deidentified individual participant data collected in this study will be available for other researchers

When the data will become available and for how long

1 year after publishing the results of study

To whom data/document is available

The data will be available for all researchers

Under which criteria data/document could be used

The data are available for all researchers who want to improve the human life quality

From where data/document is obtainable

Dr Mohammadreza Nazari 00989107001457
mohammad1992nn@gmail.com

What processes are involved for a request to access

data/document

By a phone call or leaving a message and after

informing my colleagues I will send you the scanned files

Comments