Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 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 detemine 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 recurrance rate. In spite of many hypnoic 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 fullfill study criterias will be devided in two 30 people groups randomisely. They will answer 3 questiannaire that record their depression and insomnia severity and sleep quality. Then they will recieve 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 recieves Ocimum basilicum extract and the other one recieves 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)

Phone
+98 71 4340 3712

Email address
nazari_mr@sums.ac.ir

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 betwwen 18 to 65 years old suffering from major deppresion Getting at least the score 12 out of 28 of the insomnia severity index questionnaire

Exclusion criteria:

Taking any sedative medication in last month Sufferng 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 saftwares and the code 1 and code 2 will be recorded instead of colors.) .Beacause 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 achives 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 questonnaires with the code1 or 2. Based on the order of random allocation achived 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 recieving the envelopes, the patients will open the envelope and fill the questionnaire in a seperate room. The drug and the placebo are in seperate boxes with same appearance. Each patient recieves 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 recieve. 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. Queationnaires 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 reserchers are not aware of the source of the medications the patients are recieving. Also the patients can not differentite 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 recieve. 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 Univercity 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 deprassion + 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 recieve 1100 mg of extract 1 hour before sleep each night. The patients will recieve 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

Street address
Hafez hospital, Chamran Blvd

City
Shiraz

Province
Fars

Postal code
34786-71946

Phone
+98 71 3647 9531

Email
hafezhospt@sums.ac.ir

Web page address
http://hafez.sums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr Yoones Ghasemi

Street address
Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd., Shiraz, Iran

City
Shiraz

Province
Fars

Postal code
71345-1978

Phone
+98 71 3235 7282

Email
vcrdep@sums.ac.ir

Web page address
http://research.sums.ac.ir

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
Shiraz University of Medical Sciences

Full name of responsible person
Mohammadreza Nazari

Position
Intern of medicine

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

Street address
Alavi dormitory, No 2 Alley, Mollasadra Ave, Namazi Square

City
Shiraz

Province
Fars

Postal code
7193613565

Phone
+98 71 3212 2464

Email
culture@sums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Seyed Hamdollah Mosavat

Position
Assistance proffesor

Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine

Street address
Iranian traditional medicine group, Shiraz college of medicine , Zand Blvd,

City
Shiraz

Province
Fars

Postal code
7134845794

Phone
+98 71 3234 5145

Email
hamdi_88114@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Mohammadreza Nazari

Position
Medical intern

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

Street address
Medicine college،Imam hussein square،Zand avenue

City
Shiraz

Province
Fars

Postal code
7193613565

Phone
+98 71 4340 3712

Fax

Email
nazari_mr@sums.ac.ir

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 messeage and after informing my colleagues I will send you the scanned files

Comments