

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

The effect of Ocimum Hydro Alcoholic Extract on Cognitive Function and Sleep Quality in patients with Choronic Obstructive Pulmonary Disease: A randomized controlled clinical trial

Protocol summary

Study aim

The effect of basil extract on cognitive function and sleep quality of patients with chronic obstructive pulmonary disease

Design

Clinical trial with control group, with parallel groups, Triple blind, Randomized controlled trial

Settings and conduct

The intervention will be administration of basil and placebo extract for eight weeks (60 days). The study place is in Khorramabad city.

Participants/Inclusion and exclusion criteria

1) Male and female patients 40 to 80 years old and residing in Khorramabad city 2) Sleep disorder score above 5 (based on Pittsburgh Sleep Disorders Questionnaire) 3) Cognitive dysfunction score below 26 (based on Montreal Cognitive Impairment Questionnaire); 1) Patient worsening, unstable hemodynamic status, life-threatening arrhythmias 2) neurodegenerative diseases, cancer, acute infection and known mental disorders (anxiety, depression and delirium) 3) Need for sleep medications (such as benzodiazepines, etc.) during the study

Intervention groups

The capsules will be packed in 60 envelopes at a dose of 300 mg in two envelopes A and B and delivered to the two groups of patients at the lung clinic. The capsules (containing basil and placebo extract) will be taken by patients once a night, between 22-21pm, one to two hours before bedtime, and with a glass of water.

Main outcome variables

Cognitive performance score based on Montreal questionnaire; Sleep quality score based on Pittsburgh questionnaire, And he is in the specialized clinic of Shahid Rahimi Hospital.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150919024080N15**

Registration date: **2020-03-03, 1398/12/13**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-03, 1398/12/13**

Update count: **0**

Registration date

2020-03-03, 1398/12/13

Registrant information

Name

Mohammad Gholami

Name of organization / entity

Lorestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 509 1279

Email address

gholami.m@lums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Ocimum Hydro Alcoholic Extract on Cognitive Function and Sleep Quality in patients with Chronic Obstructive Pulmonary Disease: A randomized controlled clinical trial

Public title

The effect of Ocimum on sleep and cognitive function

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Male and female patients 40 to 80 years old and residing in Khorramabad city Sleep disorder with a high score of 5 (based on Pittsburgh Sleep Disorder Questionnaire) Cognitive dysfunction score below 26 (based on Montreal Cognitive Impairment Questionnaire) No history of allergy to ocimum extract Minimum literacy and ability to understand Persian language

Exclusion criteria:

Illness, unstable hemodynamic status, life-threatening arrhythmias Affected by neurological diseases, cancer, acute infection and known mental disorders (anxiety, depression and delirium) The need for sleep medications (such as benzodiazepines, etc.) during the study Hospitalization during the study Participate in other Nairobi yoga and meditation cardiopulmonary rehabilitation programs Sensitivity to ocimum Extract for 2 consecutive days during study and non-use of ocimum Extract Capsule

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

After baseline evaluations such as pulmonary function assessment tests by a pulmonary specialist, patients are included in the study according to inclusion and exclusion criteria. Then, they will be randomly divided into two treatment and control groups. Classification is done using a random number table. Classes by age (in the two age groups below A-50 and B-50 years and older) and literacy (A-read literacy has no web-literacy) It should be noted that the volume of each block is 4 cases, thus creating 6 different combinations of 4 blocks and randomly selecting the blocks.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The capsules will be encoded by the individual as coders in two envelopes A and B. Patients will not be aware of the code allocation to the capsule envelope. Also, the researcher who provides the capsules to the clinic and the data analyst will not be aware of the contents of the envelope and the allocation of patients to the treatment and placebo groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Lorestan University of Medical Sciences

Street address

Iran University of Medical Sciences, Lorestan, Khorram Abad, 5 Km.

City

Khorram Abad

Province

Lorestan

Postal code

381351698

Approval date

2019-09-28, 1398/07/06

Ethics committee reference number

IR.LUMS.REC.1398.163

Health conditions studied

1

Description of health condition studied

Chronic obstructive pulmonary disease

ICD-10 code

J44

ICD-10 code description

Other chronic obstructive pulmonary disease

Primary outcomes

1

Description

Cognitive performance score

Timepoint

Before the intervention, and one week after the 60-day treatment period

Method of measurement

Montreal Cognitive Impairment Questionnaire

2

Description

Quality of sleep score

Timepoint

Before the intervention, and one week after the 60-day treatment period

Method of measurement

Pittsburgh Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, 60 basil capsules will be taken by patients at a dose of 300 mg once daily at 22-22 hours, one to two hours before bedtime, and with a glass of water. The drug was developed at the Razi Plant Research Center under the supervision of Lorestan University of Medical Sciences.

Category

Other

2

Description

Control group: In this group, placebo capsules (containing corn flour) will be administered by 60 patients at a dose of 300 mg once a night between 22-21pm, one to two hours before bedtime, and with a glass of water by patients. The placebo was built at the Razi Plant Research Center under the supervision of Lorestan University of Medical Sciences.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Specialty Clinic of Shahid Rahimi Hospital

Full name of responsible person

Seyed Reza Hosseini Fard

Street address

Khorramabad - Freedom Square - Mojahedin Street

City

Khorramabad

Province

Lorestan

Postal code

6814713115

Phone

+98 66 3341 9123

Email

reza.hfard@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Ebrahim Falahi

Street address

km 5 Road of Khorram Abad - Boroujerd - opposite to the Kahrizak village- Integrated Lorestan Medical Sciences Khoramabad, Lorestan, Iran

City

Khorramabad

Province

Lorestan

Postal code

381251698

Phone

+98 66 3312 0172

Email

research@lums.ac.ir

Web page address

http://research.lums.ac.ir/index.php?module=web_directory&wd_id=4664

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Khoram-Abad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Seyed Reza Hosseini Fard

Position

Undergraduate Student

Latest degree

A Level or less

Other areas of specialty/work

Nursery

Street address

km 5 Road of Khorram Abad - Boroujerd - opposite to the Kahrizak village- Integrated Lorestan Medical

City

Khorammabad
Province
Lorestan
Postal code
381351698
Phone
+98 916 018 4818
Fax
+98 66 3312 0139
Email
reza.hfard@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Mohammad Gholami
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Education
Street address
km 5 Road of Khorram Abad - Boroujerd - opposite to the Kahrizak village- Integrated Lorestan Medica
City
Khorammabad
Province
Lorestan
Postal code
381351698
Phone
+98 912 509 1279
Fax
+98 66 3312 0139
Email
gholami.m@lums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Khoram-Abad University of Medical Sciences
Full name of responsible person
Seyed Reza Hosseini Fard
Position
Undergraduate Student
Latest degree
A Level or less
Other areas of specialty/work
Nursery
Street address
Lorestan-Khorramabad- 4km Khorramabad Road, Boroujerd - Pardis University Complex - Khorramabad Nursing and Midwifery Faculty
City
Khorramabad
Province
Lorestan
Postal code
381351698
Phone
+98 916 018 4818
Email
reza.hfard@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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