

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The effect of hydroalcoholic rosemary extract on cognitive function, pulmonary function and physical activity daily of living of patients with chronic obstructive pulmonary disease

Protocol summary

Study aim

Determining the effect of hydroalcoholic rosemary extract on cognitive function, pulmonary function and physical activity daily of living of patients with chronic obstructive pulmonary disease

Design

Clinical trial with control group, with parallel groups, triple-blind, randomized control

Settings and conduct

The intervention will be the administration of rosemary extract and placebo for 8 weeks (60 days). Blinding will be done in a triple blind method

Participants/Inclusion and exclusion criteria

Patients between the ages of 40 and 80 with a diagnosis of COPD based on grade 1 to 3 GOLD criteria approved by spirometry and physician who have mild to moderate cognitive impairment based on the MMSE test with a minimum score of 23. If during the study, in addition to taking the main treatment drugs, the patient needed to take drugs that affect cognitive or pulmonary function or the amount of daily activity (such as muscle relaxants, etc) or in other pulmonary rehabilitation programs or participate in meditation and yoga or be admitted during the study.

Intervention groups

60 capsules with a dose of 500 mg will be placed in two envelopes A and B and will be given to two groups of patients in the lung clinic. The capsules contain rosemary extract and placebo (twice a day per hour). 7 to 9 in the morning and maintaining a distance of 12 hours, again at 19 to 21 at night, one to two hours before breakfast or dinner and with a glass of water will be consumed by patients. The intervention group includes 40 patients who consume rosemary capsules and in the control group there are 40 patients who consume corn flour capsules as a placebo.

Main outcome variables

Cognitive function score based on the Montreal questionnaire. Daily activity score based on the Lawton and London questionnaire. FEV1 and FVC scores and FEV1 to FVC ratios based on spirometry

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150919024080N16**

Registration date: **2020-08-25, 1399/06/04**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-25, 1399/06/04**

Update count: **0**

Registration date

2020-08-25, 1399/06/04

Registrant information

Name

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Name of organization / entity

Lorestan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2020-10-24, 1399/08/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of hydroalcoholic rosemary extract on cognitive function, pulmonary function and physical activity daily of living of patients with chronic obstructive pulmonary disease

Public title

The effect of rosemary on cognitive and pulmonary function and daily activity

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 40 and 80 years The ratio of FEV1 to FVC is less than 0.7 exhalation pressure volume per second (FEV1),less than 70% of reference value and increase in FEV1 less than 10% after inhalation of beta-two agonists Detection of COPD based on grade one to three gold criteria approved by spirometry and physician Patients with mild to moderate cognitive impairment based on MMSE test with a minimum score of 23 Have a history of smoking at least ten packs of cigarettes a year At least one year has passed since the diagnosis of COPD in the patient Do not take any herbal medicine supplements effective in improving cognitive function and lung function and daily activity (such as Ginseng,Thyme,Nigella sativa,Chamomile,etc)from two months ago No alcohol,hookah and drugs Do not take antioxidants as a supplement during the last three months(vitamin E,Omega3,α-tocopherol,etc)

Exclusion criteria:

Lack of motivation of the patient to continue cooperation Hospitalization during the study Neurological disease,cancer,acute infection and known mental disorders(anxiety,depression and delirium) Patient deterioration,unstable hemodynamic status,life threatening arrhythmias Participate in other pulmonary rehabilitation programs or meditation and yoga Do not take the capsules for two consecutive days Demonstrate sensitivity to capsules If the patient needs to take drugs that affect cognitive or pulmonary function or the amount of daily activity (such as muscle relaxants,etc)during the study,in addition to the main treatment drugs,excluded from the study Patients receiving vasodilators include organic nitrates and people with pulmonary ,hypertension,obstructive sleep apnea,malignancies,gastrointestinal abnormalities,recent surgery,severe endocrine disease,kidney disease,liver disease,inflammatory and infectious disease,and musculoskeletal disease active that causes impairment in exercise and respiratory capacity

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data and Safety Monitoring Board

Sample size

Target sample size: **80**

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. Randomisation is done using a random number table, stratification by age (in the two age groups below A-50 and B-50 years and older)and disease classes 1,2 and 3 are based on GOLD criteria and patients will be divided into two groups based on 4 or 6 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 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

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

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Province

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Approval date

2020-05-09, 1399/02/20

Ethics committee reference number

IR.LUMS.REC.1399.044

Health conditions studied

1

Description of health condition studied

COPD

ICD-10 code

J44

ICD-10 code description

other chronic obstructive pulmonary disease

Primary outcomes

1

Description

Cognitive function

Timepoint

Before starting treatment and one week after completing the 60 day treatment period

Method of measurement

Montreal Cognitive Dysfunction Questionnaire

2

Description

Pulmonary function

Timepoint

Before starting treatment and one week after completing the 60 day treatment period

Method of measurement

Spirometry device

3

Description

Activity daily of living

Timepoint

Before starting treatment and one week after completing the 60 day treatment period

Method of measurement

Lawton and London Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group,60 capsules of rosemary extract with a dose of 500 mg twice at 7 to 9 in the morning and maintaining a distance of 12 hours,again at 19 to 21 at night,one to two hours before breakfast or dinner and they will be consumed by patients with a glass of water.this drug is prepared by Goldaro Pharmaceutical Company located in Isfahan and is

weighed and packaged in a sterile environment inside 500 mg capsules by the expert of Khorman Daru Khorramabad Company.

Category

Other

2

Description

Control group: In this group,60 capsules of Placebo (containing corn flour) with a dose of 500 mg twice at 7 to 9 in the morning and maintaining a distance of 12 hours,again at 19 to 21 at night,one to two hours before breakfast or dinner and they will be consumed by patients with a glass of water.the placebo is prepared and weighed by Khoraman Daroo Company.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rahimi Hospital Specialized Clinic

Full name of responsible person

Arash momeni safarabadi

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Khoramabad-Razi Square-Alley Arasteh One

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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?

No

Title of funding source
Khorramabad University of Medical Sciences
Proportion provided by this source

1

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
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Khoram-Abad University of Medical Sciences

Full name of responsible person
Arash momeni safarabadi

Position
Master student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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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