

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Zofa (*Nepeta bracteata* Benth.) Product on Spirometric Parameters and Respiratory Symptoms in the Patients with Mild to Moderate Chronic Obstructive Pulmonary Disease

Protocol summary

Summary

This is a double blind study, for assessing the effect of Zofa (*Nepeta Bracteata* Benth.) syrup and placebo on the treatment of Chronic Obstructive Pulmonary Disease. Qualified patients that fulfilled for inclusion criteria as the Mild to Moderate COPD, age of 18 and more, no allergy to the Lamiaceae family, no lactation or pregnancy, not having Diabetes and history of epilepsy and seizure. Patients in the exacerbation period are excluded. The sample size in each group is 30 (case and control). The dose of zofa (*Nepeta Bracteata* Benth.) syrup and placebo syrup is three times per day and each time 10 cc. The diagnosis is confirmed by a Pulmonologist through history and clinical examination. The patients are randomly divided to two groups of placebo and intervention by the random number table. Before entering the study, the required information is taken by the project agent and after receiving a written signed consent form and demographic questionnaire is filled. A standard questionnaire of Chronic Obstructive Pulmonary Disease Assessment Test (CAT) includes constituent items such as cough, production of phlegm and chest tightness is filled before, two and four weeks after intervention. Spirometry will be done before and after four weeks of intervention. At the end of the study, relevant information is extracted and analyzed.

General information

Acronym

COPD (Chronic Obstructive Pulmonary Disease)

IRCT registration information

IRCT registration number: **IRCT2015121925598N1**

Registration date: **2016-03-24, 1395/01/05**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-03-24, 1395/01/05

Registrant information

Name

Ali Abdolahinia

Name of organization / entity

Shahed University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research. Shahed University

Expected recruitment start date

2016-04-02, 1395/01/14

Expected recruitment end date

2016-08-10, 1395/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Zofa (*Nepeta bracteata* Benth.) Product on Spirometric Parameters and Respiratory Symptoms in the Patients with Mild to Moderate Chronic Obstructive Pulmonary Disease

Public title

Effect of Zofa (*Nepeta bracteata* Benth.) Product on

Chronic Obstructive Pulmonary Disease

Purpose

Treatment

Inclusion/Exclusion criteria

Including criteria: Mild to Moderate Chronic Obstructive Pulmonary Disease; Age 18 and more; no allergy to the Lamiaceae family; no lactation or pregnancy; not having Diabetes and history of epilepsy and seizure Excluding criteria: Exacerbation period

Age

From **18 years** old to **139 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahed University

Street address

No.1471, Between Forsat and Nosrat St, North Kargar Ave

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Postal code

-

Approval date

2016-02-09, 1394/11/20

Ethics committee reference number

IR.Shahed.REC.1394.84

Health conditions studied

1

Description of health condition studied

Chronic Obstractive Pulmonary Disease

ICD-10 code

J44.8

ICD-10 code description

Other specified chronic obstructive pulmonary disease

Primary outcomes

1

Description

Evaluation of quality of life of patients

Timepoint

The time of study inclusion and two and four weeks later.

Method of measurement

COPD Assessment Test (CAT) Questionnair

2

Description

Change of FEV1 (Forced Expiratory volume in 1 second)

Timepoint

Before treatment and four weeks after treatment

Method of measurement

Spirometry super Spiro, Micro medical company, England.

Secondary outcomes

empty

Intervention groups

1

Description

Zofa Product (Syrup),Oral, 10cc, Three times of day for four weeks

Category

Treatment - Drugs

2

Description

Placebo Product (Syrup), Oral. 10 cc, Three times a day for four weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Masih Daneshvari Hospital

Full name of responsible person

Ali Abdolahinia

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End of Porebtehaj St, Darabad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahed University

Full name of responsible person

Dr. Mohsen Naseri

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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

Vice chancellor for research, Shahed University

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty
Clinical Study Report
empty
Analytic Code

empty
Data Dictionary
empty