

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The effect of *Thymus Vulgaris* inhaling on respiratory status in patients with exacerbation of Chronic Obstructive Pulmonary disease

Protocol summary

Summary

Objectives: One of the most common respiratory diseases is Chronic obstructive pulmonary disease Which have periods of acute exacerbation. This study survey the effect of *Thymus Vulgaris* inhaling on respiratory status of these patients. Design: This study is a blind randomized clinical trial so that researchers (collectors of questionnaires) will be blind about allocation of patients to control and intervention groups. Setting and conduct: The sample includes 60 patients with acute exacerbation of chronic obstructive pulmonary disease referred to the emergency department of 22 Bahman hospital of Gonabad. The patients were selected by convenience sampling and they will be allocated alternately in control and intervention groups. Improvement in respiratory status will be measured by reduced respiratory rate, increase in arterial oxygen saturation and Wheezing decline in lung lobes. In the intervention group, one percent *Thymus Vulgaris* inhaling that has been made by Exir gole sorkh Company will be used as much as 5 ml for the duration of 15 minutes with a inhaling treatment mask. In control group, distilled water inhaling will be received by the patients in the same amount and in the same duration. After the intervention, Information on dependent variables: respiratory rate, arterial oxygen saturation and wheezing will be collected by a research assistant who is not aware of intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017020732436N1**

Registration date: **2017-06-11, 1396/03/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-06-11, 1396/03/21

Registrant information

Name

Elyas Hosseinzadeh

Name of organization / entity

Gonabad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 5723 6083

Email address

e.hosseinzadeh@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Gonabad University of Medical Sciences

Expected recruitment start date

2017-03-10, 1395/12/20

Expected recruitment end date

2017-04-09, 1396/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of *Thymus Vulgaris* inhaling on respiratory status in patients with exacerbation of Chronic Obstructive Pulmonary disease

Public title

The effect of *Thymus Vulgaris* inhaling on Chronic Obstructive Pulmonary disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: No anatomic face problem; Agree to participate in the research; oriented in time, place and person; Age between 50 and 80 years; not being allergic to perfumes and essences. Exclusion criteria: Pregnancy; Nausea and vomiting; Intolerance to the mask used for inhalation therapy.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Samples will be divided into two experimental and control groups based on permutation blocks (blocks of size 4). It will be listed according to six possible ways (AABB, ABAB, ...) randomly and the arrangement of receiving intervention will be determined accordingly. For blinding the questionnaire will be completed by a person who is not aware of the research unit in the control group or the experimental group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Gonabad University of Medical Sciences

Street address

Next to the Asian Road

City

Gonabad

Postal code

Approval date

2016-08-06, 1395/05/16

Ethics committee reference number

IR.Gmu.REC.1395.51

Health conditions studied

1

Description of health condition studied

Exacerbation Of Chronic Obstructive Pulmonary Disease

ICD-10 code

J44.1

ICD-10 code description

Chronic obstructive pulmonary disease with acute exacerbation, unspecified

Primary outcomes

1

Description

Respiratory Rate

Timepoint

Before and after intervention

Method of measurement

Count chest movement during respiration

2

Description

Arterial blood oxygen saturation

Timepoint

Before and after intervention

Method of measurement

Finger Pulse Oximeter

3

Description

Wheezing

Timepoint

Before and after intervention

Method of measurement

Lung sounds auscultation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: one percent Thymus Vulgaris inhaling will be used as much as 5 ml for the duration of 15 minutes through inhaling treatment mask at the time of patients' admission who are suffering from chronic obstructive pulmonary disease exacerbation (just for one time).

Category

Treatment - Other

2

Description

Control group: Distilled water inhaling will be used as much as 5 ml for the duration of 15 minutes with inhaling treatment mask at the time of patients' admission who

are suffering from chronic obstructive pulmonary disease exacerbation (just for one time).

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

22 Bahman Hospital

Full name of responsible person

Elyas Hosseinzadeh Yonesi

Street address

22 Bahman Hospital, Naserkhosro Street, Gonabad,
Khorasan-e- Razavi

City

Gonabad

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for Research of Gonabad University of
Medical Sciences

Full name of responsible person

Dr. Alireza Mohammadzadeh

Street address

Gonabad University of Medical Sciences, Next to the
Asian Road

City

Gonabad

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 of Gonabad University of
Medical Sciences

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**Contact****Name of organization / entity**

Gonabad University of Medical Sciences

Full name of responsible person

Elyas Hosseinzadeh Yonesi

Position

Student of Msc in Critical Nursing

Other areas of specialty/work**Street address**

Gonabad University of Medical Sciences, next to the
Asian road

City

Gonabad

Postal code**Phone**

+98 51 5722 5027

Fax**Email**

e.hosseinzadeh@gmu.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Gonabad University of Medical Sciences

Full name of responsible person

Mohammad Mojalli

Position

PhD in Nursing Education

Other areas of specialty/work**Street address**

Gonabad University of Medical Sciences, next to the
Asian road

City

Gonabad

Postal code**Phone**

+98 51 5722 5027

Fax**Email**

mmojali@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Gonabad University of Medical Sciences

Full name of responsible person

Elyas Hosseinzadeh Yonesi

Position

Student of Msc in Critical Nursing

Other areas of specialty/work**Street address**

Next to the Asian Road

City

Gonabad

Postal code**Phone**

+98 51 5722 5027

Fax**Email**

e.hosseinzadeh@gmu.ac.ir

Web page address

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