

# 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**

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**Position**

Student of Msc in Critical Nursing

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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*