

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Evaluating the impact of saturated steam with salt in improving pulmonary tests results and status of patients with Chronic Obstructive Pulmonary Disease attend in Dr. Masih Daneshvary hospital of Tehran in 1395 to 1396

Protocol summary

Summary

Since few studies have been evaluated the impact of Halotherapy on COPD symptoms, the aim of current study is evaluating the impact of Halotherapy on improving pulmonary tests results and status of patients with Chronic Obstructive Pulmonary Disease referred to Dr. Masih Daneshvary hospital of Tehran. Methods: In this double blind clinical trial, 85 patients with COPD who are in stable condition are randomly divided into two groups after recording their information on disease. Study is starting in autumn 2016. After two months treatment with Saltair by salt natural crystals or placebo, patients were re-examined and entered to a phase of clearance. Then patients attended in hospital for next visit by physician and after recording data, groups were crossed-over and treated for next two months of drug and placebo.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016080927995N2**

Registration date: **2016-11-26, 1395/09/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-11-26, 1395/09/06

Registrant information

Name

Alireza Eslaminejad

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences, National Research Institute of Tuberculosis and Lung Diseases (NRITLD)

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-09-21, 1396/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the impact of saturated steam with salt in improving pulmonary tests results and status of patients with Chronic Obstructive Pulmonary Disease attend in Dr. Masih Daneshvary hospital of Tehran in 1395 to 1396

Public title

Evaluating the impact of Halotherapy on improving pulmonary tests results and status of patients with Chronic Obstructive Pulmonary Disease referred to Dr. Masih Daneshvary hospital of Tehran in 2016 to 2017

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: COPD patients regarding GOLD criteria; Stable patients older 18 years . Exclusion criteria: History of surgery in thorax; COPD exacerbation; Unbearable complications of COPD; Huge changes in treatment regimen; Missing patients through out the study; Irregular treatment; Smoking; Exacerbation in comorbidities like CHF, CRF, etc.

Age

From **18 years** old to **99 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences,
Yanan, Velenjak, Tehran

City

Tehran

Postal code

Approval date

2011-06-26, 1390/04/05

Ethics committee reference number

Sbmu1.REC.1390.22

Health conditions studied

1

Description of health condition studied

Chronic obstructive pulmonary disease

ICD-10 code

J44.9

ICD-10 code description

Chronic obstructive: airway disease NOS lung disease
NOS

Primary outcomes

1

Description

The walked distance

Timepoint

two month after first visit

Method of measurement

6MWT

2

Description

forced vital capacity

Timepoint

two month after study beginning

Method of measurement

spirometry

3

Description

forced expiratory volume

Timepoint

two month after study beginning

Method of measurement

spirometry

4

Description

Minute

Timepoint

2 month after first visit

Method of measurement

6MWD

Secondary outcomes

1

Description

Disease manifestation

Timepoint

2 month after first visit

Method of measurement

Asking patients

2

Description

Exacerbation rate

Timepoint

Every other month

Method of measurement

Asking patients

Intervention groups

1

Description

A kind of inhalation therapy with a mineral salt as an alternative treatment named halotherapy twice a day each for 30 minutes for 2-months

Category

Treatment - Drugs

2

Description

Patients in control group use plastic contained Saltairs which have no inhaler in it actually as placebo drug.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital NRITLD

Full name of responsible person

Alireza Eslaminejad

Street address

Masih Daneshvari Hospital, Daarabad, Niavaran, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Alireza Eslaminejad

Street address

Masih Daneshvari Hospital, Daarabad, Niavaran, Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Other areas of specialty/work

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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