

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Evaluating the Effect of Wet Cupping on health-related quality of life in the Patients with Moderate Chronic Obstructive Pulmonary Disease

Protocol summary

Study aim

The effect of wet cupping on quality of life in chronic obstructive pulmonary disease

Design

Clinical trial with control group, Parallel, Not blinded, Randomized Sample size: 56

Settings and conduct

Patients aged 30 to 60 years with moderate type of chronic obstructive pulmonary disease who are referred to Loghman Hospital Lung Clinic on an Outpatient basis are randomly divided into intervention and control groups. The diagnosis is confirmed by a Pulmonologist through history and clinical examination. The sample size in each group is 28 (case and control). Both groups receive their standard treatment. The wet cupping is performed on one of the days of 17, 19 and 21 lunar months. 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, one and three weeks after intervention. At the end of the study, relevant information is extracted and analyzed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Moderate Chronic Obstructive Pulmonary Disease; from 30 years old to 60 years old; personal satisfaction
Exclusion criteria: History of anemia; history of coagulation diseases; history of treatment with wet cupping in the last 1 month; lactation; pregnancy; exacerbation period; Patients with underlying diseases such as Cystic fibrosis, bronchopulmonary dysplasia, heart failure, bronchotracheomalacia, bronchiectasis, pulmonary embolism, and sarcoidosis; patients who are taking medications such as aspirin, beta blocker and non-steroidal anti-inflammatory drugs (NSAIDs).

Intervention groups

1. First group: Standard treatment + Wet cupping
2. Second group: Standard treatment (Spray Symbicort + Spray Atrovent or Spray Pulmicort + Spray Formoterol +

Spray Tiotropium)

Main outcome variables

Assess patient quality of life

General information

Reason for update

Acronym

COPD (Chronic Obstructive Pulmonary Disease)

IRCT registration information

IRCT registration number: **IRCT20200101045976N1**

Registration date: **2020-02-06, 1398/11/17**

Registration timing: **prospective**

Last update: **2020-02-06, 1398/11/17**

Update count: **0**

Registration date

2020-02-06, 1398/11/17

Registrant information

Name

Roya Baniamerian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4467 3971

Email address

dr-baniamerian@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-17, 1398/11/28

Expected recruitment end date

2020-05-20, 1399/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the Effect of Wet Cupping on health-related quality of life in the Patients with Moderate Chronic Obstructive Pulmonary Disease

Public title

Evaluating the Effect of Wet Cupping on quality of life in the Patients with Chronic Obstructive Pulmonary Disease

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with moderate COPD diagnosed by lung specialty From 30 years old to 60 years old Individual willingness and satisfaction to enter the study stable clinical condition The same type of medication used

Exclusion criteria:

Patients with a history of anemia Patients with a history of coagulopathy History of treatment with wet cupping in the last 1 month Lactation Pregnancy Patients with severe COPD and need hospitalization Patients with underlying diseases such Cystic fibrosis, bronchopulmonary dysplasia, heart failure, bronchotracheomalacia, bronchiectasis, pulmonary embolism, and sarcoidosis Patients taking drugs such as aspirin, beta-blocker and non-steroidal anti-inflammatory drugs (NSAIDs)

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, after calculating the final sample size of the study, random chains are generated on the basis of simple random series using quadratic random blocks for both intervention and control groups. For the generated random chain, a corresponding code will be generated for each sequence. This code contains two letters of the alphabet and one number. Anonymous codes will be posted on the forms before the study begins. During the study, patients were divided into two groups according to the order of entry of patients and randomization sheets (merely including anonymous codes). Patients in the intervention group will receive wet cupping in addition to routine treatment. Patients in the control group will receive only routine treatment.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2019-12-31, 1398/10/10

Ethics committee reference number

IR.SBMU.RETECH.REC.1398.493

Health conditions studied**1****Description of health condition studied**

Chronic obstructive pulmonary disease

ICD-10 code

J44.9

ICD-10 code description

Chronic obstructive pulmonary disease, unspecified

Primary outcomes**1****Description**

Evaluation of quality of life of patients

Timepoint

The time of study inclusion and one and three weeks later.

Method of measurement

COPD Assessment Test (CAT) Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Wet cupping(between the two scapulas) [Wet-cupping will be performed by a physician on one of the days of 17, 19 and 21 lunar months. Intervention will done only once. Wet-cupping treatment procedure will last about 10 min and will be conducted in three steps.) + Standard treatment [Symbicort spray 320 mcg one puff every 12 hours(Symbicort contains a combination of budesonide 320 mcg and formoterol 9mcg), manufacturing Company: AstraZeneca Duration of use:One Month and Atrovent spray one puff every 8 hours(Atrovent Inhaler 20 mcg/dose) manufacturing Company: BOEHRINGER INGELHEIM Duration of use:One Month or Pulmicort spray 200 one puff every 12 hours(Each metered dose contains 200 micrograms of budesonide) manufacturing Company: AstraZeneca Duration of use:One Month and Foradil spray one puff every 12 hours (each capsule contains 12 micrograms formoterol) manufacturing Company: Novartis duration of use:one month and Thiotropium spray one puff every morning (each capsule contains: Thiotropium 18 mcg) manufacturing Company: BOEHRINGER INGELHEIM duration of use:one month]

Category

Treatment - Devices

2

Description

Control group: Standard treatment [Symbicort spray 320 mcg one puff every 12 hours(Symbicort contains a combination of budesonide 320 mcg and formoterol 9mcg), manufacturing Company: AstraZeneca Duration of use:One Month and Atrovent spray one puff every 8 hours(Atrovent Inhaler 20 mcg/dose) manufacturing Company: BOEHRINGER INGELHEIM Duration of use:One Month or Pulmicort spray 200 one puff every 12 hours(Each metered dose contains 200 micrograms of budesonide) manufacturing Company: AstraZeneca Duration of use:One Month and Foradil spray one puff every 12 hours (each capsule contains 12 micrograms formoterol) manufacturing Company: Novartis duration of use:one month and Thiotropium spray one puff every morning (each capsule contains: Thiotropium 18 mcg) manufacturing Company: BOEHRINGER INGELHEIM duration of use:one month]

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman Hakim Hospital

Full name of responsible person

Roya Baniamerian

Street address

Loghman Hakim Hospital, Lashkar Ave, Tehran, Iran

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Province

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Email

dr-baniamerian@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sponsor Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Street address

Tehran - Shahid Beheshti University of Medical Sciences, Next to Taleghani Hospital, Yemen St., Chamran Highway

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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

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Roya Baniamerian

Position

Physician, PhD student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Roya Baniamerian

Position

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Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Roya Baniamerian

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Publishing results in form of a PhD thesis and an article indexing in ISI

When the data will become available and for how long

after PhD thesis defence

To whom data/document is available

Public

Under which criteria data/document could be used

for research reasons

From where data/document is obtainable

Shahid Beheshti University of Medical Sciences

What processes are involved for a request to access data/document

approving by responsible officer

Comments