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 is28 (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 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)

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+98 21 4467 3971

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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) Questionnair

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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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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Other areas of specialty/work
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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