Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of compound "Ma-ol-asal" on clinical manifestations and quality of life of chronic obstructive pulmonary disease (COPD) patients

Protocol summary

Study aim
In this study, the effectiveness of compound "Ma-ol-asal" syrup is measured on the improvement of clinical signs and quality of life of chronic obstructive pulmonary disease (COPD).

Design
Randomized, double blind, with control group, Clinical trials

Settings and conduct
Patients who refer to in pulmonary clinic ,at first, an examination and spiromety is done for them.Then, they complete CAT and St. Georges respiratory questionnaires. With randomization (blocks), Patients will be divided into 2 groups of 38 people: Intervention Group (Ma-ol-asal", Oral Syrup, 10 ml third a day) and Control Group (placebo, Oral Syrup, 10 ml third a day). Patients will be treated for 8 weeks.

Participants/Inclusion and exclusion criteria
Inclusion criteria: participate to study, not allergic to any of the components of the drug; Exclusion criteria: very severe disease and/or severe and requiring hospitalization, underlying conditions (CF, bronchopulmonary, dysplasia, heart failure, bronchiectasis, pulmonary embolism and sarcoidosis) and Taking drugs such as aspirin, beta-blocker, and NSAID.

Intervention groups
Experimental group, receive the standard treatment and "Ma-ol-asal"syrup.Control group, patients receive standard treatment and placebo.

Main outcome variables
Clinical manifestation, Quality of Life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190217042737N2**
Registration date: **2020-04-04, 1399/01/16**
Registration timing: **retrospective**

Last update: **2020-04-04, 1399/01/16**
Update count: **0**

Registration date
2020-04-04, 1399/01/16

Registrant information

Name
Zohreh Poursaleh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 7787 7434

Email address
zpoursaleh7@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-03-21, 1397/01/01

Expected recruitment end date
2020-01-21, 1398/11/01

Actual recruitment start date
2018-03-21, 1397/01/01

Actual recruitment end date
2020-01-21, 1398/11/01

Trial completion date
2020-01-21, 1398/11/01

Scientific title
The effect of compound "Ma-ol-asal" on clinical manifestations and quality of life of chronic obstructive pulmonary disease (COPD) patients

Public title
The effect of compound "Ma-ol-asal" of chronic

obstructive pulmonary disease (COPD) patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with COPD referring to the lung clinic People who are willing to participate in the study.

Exclusion criteria:

Very severe COPD require hospitalization Underlying illnesses, such as CF, Broncho-pulmonary dysplasia, heart failure, broncho-tracheomalacia, bronchiectasis, pulmonary embolism and sarcoidosis. Taking drugs such as aspirin, beta-blocker and NSAID. Allergic to any of the components of "Ma-ol-asal"

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **76**

Actual sample size reached: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on four randomized chains and blocks of four, Patients will be divided into 2 groups of 38 people: Intervention Group and Control Group. Patients will be treated for 8 weeks.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, major researcher, lung specialist, respiratory testing technician, use of placebo

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Baqiatallah University of Medical Sciences

Street address

Nasri St.,South Sheikh Baha'i avenue.,Mulla- Sadra Avenue.,Vanak Square

City

Tehran

Province

Tehran

Postal code

1435916471

Approval date

2017-11-03, 1396/08/12

Ethics committee reference number

IR.BMSU.REC.1396.399

Health conditions studied

1

Description of health condition studied

Chronic Obstructive Pulmonary Disease (COPD)

ICD-10 code

J44.9

ICD-10 code description

Chronic obstructive pulmonary disease, unspecified

Primary outcomes

1

Description

Clinical symptoms

Timepoint

At the beginning of the study (before the intervention) and 8 weeks after commencing consumption of the compound syrup

Method of measurement

CAT questionnaire

2

Description

Quality of life

Timepoint

At the beginning of the study (before the intervention) and 8 weeks after commencing consumption of the compound syrup

Method of measurement

The St George's respiratory questionnaire

Secondary outcomes

1

Description

Respiratory test changes in FEV1, FEV1 / FVC

Timepoint

At the beginning of the study (before the intervention) and 8 weeks after commencement of the administration of the compound syrup

Method of measurement

Pulmonary functional test

Intervention groups

1

Description
Intervention group: Oral syrup,compound "Ma-ol-asal Syrup contains honey, ginger, cinnamon, cardamom, saffron, Alpinia officinarum, oral syrup (250ml),10 ml three times a day,for 8 weeks.
Category
Treatment - Drugs

2

Description
Control group: Oral syrup, a mixture of honey, water, color additive, etc. Oral Syrup (250ml), 10 ml three times a day, for 8 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Polyclinic Bahaqiallah
Full name of responsible person
Zohreh Poursaleh
Street address
Mulla-Sadra St; Vanak Squa
City
Tehran
Province
Tehran
Postal code
1435916471
Phone
+98 21 8216 2314
Email
z_poursaleh@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Deputy of Research and Technology University
Street address
Mulla-Sadra St, Vanak Squa.
City
Tehran
Province
Tehran
Postal code
1435916471
Phone
+98 21 8248 2503
Email
z_poursaleh@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bagheiat-allah 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
Zohreh Poursaleh
Position
Consultant
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
Street address
Mulla- Sadra St, Vanak Squa.
City
Tehran
Province
Tehran
Postal code
1435916471
Phone
+98 21 8248 2503
Email
z_poursaleh@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mostafa Ghanei/ Rasul Choopani
Position
Professor/Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Pulmonologist/ Traditional medicine
Street address

Shahid Beheshti Faculty of Medicine-No. 8.,Shams Alley.,Tavanir Cross., Vali Asr St., Vanak Square.

City
Tehran

Province
Tehran

Postal code
1516745811

Phone
+98 912 379 0148

Fax

Email
rchoopani@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Zohreh Poursaleh

Position
Candidate of PhD

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

Street address
Shahid Beheshti Faculty of Medicine-No. 8.,Shams Alley.,Tavanir Cross., Vali Asr St., Vanak Square.

City
Tehran

Province
Tehran

Postal code
1516745811

Phone
+98 21 7787 7434

Fax

Email
zpoursaleh7@sbmu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No more information.

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable