

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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)

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+98 21 7787 7434

Email address

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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

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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

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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

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

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Person responsible for scientific inquiries

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Full name of responsible person

Mostafa Ghanei/ Rasul Choopani

Position

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Latest degree

Ph.D.

Other areas of specialty/work

Pulmonologist/ Traditional medicine

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Latest degree

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Other areas of specialty/work

Traditional Medicine

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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