Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of compound "Ma-ol-asal" on clinical manifestation of the adult asthma

Protocol summary

Study aim
evaluation of the effect of compound "Ma-ol-asal" on clinical manifestation of the adult asthma 18-60 years old

Design
After getting Ethics committee reference number and IRCT registration, patients who have mild to moderate asthma 18-60 years that have diagnosed by lung specialist and have inclusion criteria, divide to case and control group.

Settings and conduct
taking a history. all patients were carefully examined, completed a Asthma Control Test (ACT). The classic treatment of asthma was performed for both groups, which include the use of fluticasone spray 250/25 mcg1 puff every 12 hours. In addition to the aforementioned treatment, the experimental group also receive compound "Ma-ol-asal".

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients with asthma 18-60 years old that is referred to the pulmonary clinic of the Loghman Hospital Exclusion criteria: under 18 and over 60 years old patients with severe asthma and require hospitalization patients with underlying diseases such as CF,COPD, heart failure, GERD, bronchiectasis, Pulmonary embolism and sarcoidosis Addicts to cigarettes BMI > 29 pregnant and lactating women

Intervention groups
Asthmatic patients who receive compound "Ma-ol-asal" and classic treatment. Asthmatic patients who receive placebo and classic treatment.

Main outcome variables
Shortness of breath Cough Wheez Spray intake Patient's function Asthma control rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181115041664N1**
Registration date: **2020-05-10, 1399/02/21**
Registration timing: **retrospective**

Last update: **2020-05-10, 1399/02/21**
Update count: **0**

Registration date
2020-05-10, 1399/02/21

Registrant information

Name
Narges Kaveh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8877 3521

Email address
nkaveh@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-23, 1397/07/01

Expected recruitment end date
2018-12-21, 1397/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of compound "Ma-ol-asal" on clinical manifestation of the adult asthma

Public title

The effect of compound "Ma-ol-asal" on treatment of the adult asthma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

mild to moderate asthma 18-60 years old Referral to the pulmonary clinic of Loghman Hospital, Tehran, Iran

Exclusion criteria:

under 18 and over 60 years old patients with severe asthma and require hospitalization patients with underlying diseases such as CF,COPD, heart failure, GERD, bronchiectasis, Pulmonary embolism and sarcoidosis Addicts to cigarettes BMI > 29 pregnant and lactating women

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization: Block Randomization unit: Individual Randomization tool: Random numbers table How to build a sequence: In the random numbers table, the random number is selected from the table and is selected in rows or columns in the up and down and left or right directions of the next. Because amount of 4 blocks conditions for the two groups is six, the numbers are greater than 6 and the zero ignored and each digit identifies the block.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients enter the study after studying and completing the form of informed consent and knowledge that drugs and placebo are not known. The researcher does not know the drug cods for medication or placebo.

Placebo

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

The Office of Management Research, Shahid Beheshti University of Medical Sciences, next to Taleghani Hospital, Evin, Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2019-01-06, 1397/10/16

Ethics committee reference number

IR.SBMU.RETECH.REC.1397.828

Health conditions studied

1

Description of health condition studied

Asthma

ICD-10 code

J45

ICD-10 code description

Asthma

Primary outcomes

1

Description

Breathlessness

Timepoint

Before and after the intervention

Method of measurement

Asthma control Test

2

Description

Cough

Timepoint

Before and after the intervention

Method of measurement

Asthma control Test

3

Description

Wheez

Timepoint

Before and after the intervention

Method of measurement

Asthma control Test

4

Description

Spray Intake

Timepoint

Before and after the intervention
Method of measurement
Asthma control Test

5

Description
Patient`s function
Timepoint
Before and after the intervention
Method of measurement
Asthma control Test

6

Description
Asthma control rate
Timepoint
Before and after the intervention
Method of measurement
Asthma control Test

7

Description
B.M.I
Timepoint
Before and after the intervention
Method of measurement
kg/m2

Secondary outcomes

1

Description
-
Timepoint
-
Method of measurement
-

Intervention groups

1

Description
Intervention group: receiver 10cc syrup in 100cc lukewarm water, 3 times per day with Seretide spray 1 puff every 12 hours for 3 months. Each 100cc of compound honey syrup contains 2 gr. of Cinnamomum verum, 2 gr. of Elettaria cardamomum, 1 gr.Zingiber officinalRoscoe, 1 gr. Alpinia galangal and 1 gr. Crocus sativus with water and honey. Medicine is provided by Niac company.
Category
Treatment - Drugs

2

Description
Control group: Receiver 10cc placebo in 100cc lukewarm water, 3 times per day with Seretide spray 1 puff every 12 hours for 3 months. Each 100cc of placebo syrup contains 0.1% sodium benzoate, 0.1% saccharin and 0.25% C.M.G. Placebo is provided by Niac company.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Loghman hospital
Full name of responsible person
Narges Kaveh
Street address
Shams Alley, Valiasr Avenue
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Rasool Choopani
Street address
Shahid Beheshti University of Medical Sciences, Next to Taleghani Hospital, Evin, Shahid Chamran Highway, Shahid Beheshti University of Medical Sciences
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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
Narges Kaveh
Position
PhD candidate
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
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Person responsible for updating data

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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
We have not got any plans for dispersion.
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available