Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

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

Protocol summary

Summary

Purpose of this study is evaluation of the effect of compound "Ma-ol-asal" on clinical manifestation of the pediatric asthma in children 6-16 years old that is referred to the pulmonary clinic of the Mofid Children's Hospital in 2015.This study is a randomized clinical trial. Inclusion criteria: patients with asthma 6-16 years old that is referred to the pulmonary clinic of the Mofid Children's Hospital(Tehran, Iran) and patients who are willing and consent to participate in the study. Exclusion criteria: patients under 6 and over 16 years old; patients with moderate asthma; patients with severe asthma; patients requiring hospitalization and patients who have attack; patients with underlying diseases such as CF, Bronchopulmonary dysplasia, heart failure, bronchotracheomalacia, GERD, bronchiectasis, Pulmonary embolism and sarcoidosis; patients who are taking medications such as aspirin, beta blocker and NSAID's; patients who become affected to other acute disease during the study. Patients who are allergic to any components of compound "Ma-ol-asal" and patients who have decision to excluded from the study. This study includes 80 Patients. In this study After taking a history of the patient, all the selected cases were carefully examined, completed a Asthma Control Questionnaire (ACQ), performed spirometry and records were maintained. The classic treatment of asthma was performed for both groups, which include the use of fluticasone spray 50 mcg 2 puffs every 12 hours and salbutamol that was used in cases of exacerbated their symptoms. In addition to the aforementioned treatment, the experimental group also receive compound "Ma-ol-asal". Dosage of the compound "Ma-ol-asal" is 10 ml with 100 ml tepid water, three times a day. Time study is 8 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015083123834N1**
Registration date: **2015-09-16, 1394/06/25**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-09-16, 1394/06/25

Registrant information

Name

Shahpar Kaveh Bagh Bahadorani

Name of organization / entity

Shahid Beheshti University of Medical Sciences, School of Traditional Medicine

Country

Iran (Islamic Republic of)

Phone

+98 21 8877 6327

Email address

skaveh83@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2015-09-06, 1394/06/15

Expected recruitment end date

2016-01-20, 1394/10/30

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 pediatric asthma

Public title
The effect of compound "Ma-ol-asal" on treatment of the pediatric asthma
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: patients with asthma aged 6-16 years old that referred to the pulmonary clinic of the Mofid Children's Hospital, Tehran, Iran; patients who are willing and consent to participate in the study. Exclusion criteria: Patients under 6 and over 16 yearsold; patients with modprate asthma; patients with severe asthma; patients requiring hospitalization and patients who have attack; patients with underlying diseases such as CF, Bronchopulmonary dysplasia, heart failure, bronchotracheomalacia, GERD, bronchiectasis, Pulmonary embolism and sarcoidosis; patients who are taking medications such as aspirin, beta blocker and NSAID's; patients who become affected to other acute disease during the study; patients who are allergic to any components of compound "Ma-ol-asal" and request and patients who have decision to excluded from the study.
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
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
Shahid Beheshti University of Medical Sciences Ethics Committee
Street address
The Office of Management Research, Shahid Beheshti University of Medical Sciences, next to Taleghani Hospital, Evin, Shahid Chamran Highway
City
Tehran
Postal code
Approval date
2015-08-05, 1394/05/14
Ethics committee reference number
IR.SBMU.REC.172

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 the intervention, and at the end of eghth week (end of the intervention)
Method of measurement
Asthma Control Questionnaire

2

Description
Cough
Timepoint
Before the intervention, and at the end of eghth week (end of the intervention)
Method of measurement
Asthma Control Questionnaire

3

Description
Wheez
Timepoint
Before the intervention, and at the end of eghth week (end of the intervention)
Method of measurement
Asthma Control Questionnaire

4

Description
FEV1
Timepoint
Before the intervention, and at the end of eghth week (end of the intervention
Method of measurement
Spirometry

5

Description
FVC
Timepoint
Before the intervention, and at the end of eghth week (end of the intervention)
Method of measurement
Spirometry

6

Description
FEF25-75
Timepoint
Before the intervention, and at the end of eghth week (end of the intervention)
Method of measurement
Spirometry

7

Description
FEV1/ FVC
Timepoint
Before the intervention, and at the end of eghth week (end of the intervention)
Method of measurement
Spirometry

8

Description
Allergic rhinitis
Timepoint
Before the intervention, and at the end of eghth week (end of the intervention)
Method of measurement
Examination

Secondary outcomes

1

Description
BMI
Timepoint
Before the intervention and after the intervention
Method of measurement
kg/m2

Intervention groups

1

Description
Intervention group: Fluticasone spray 50 mcg 2 puffs every 12 hours and salbutamol that was used in cases of exacerbated their symptoms. In addition to the aforementioned treatment, the experimental group also receive compound
Category
Treatment - Drugs

2

Description
Control group: Fluticasone spray 50 mcg 2 puffs every 12 hours and salbutamol that was used in cases of exacerbated their symptoms
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Pulmonary clinic of the Mofid Children's Hospital
Full name of responsible person
Shahpar Kaveh Bagh Bahadorani
Street address
Mofid Children's Hospital, Shariati Ave.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Mahmood Mosadegh
Street address
Shahid Beheshti University of Medical Sciences, Next to Taleghani Hospital, Evin, Shahid Chamran Highway, Shahid Beheshti University of Medical Sciences
City
Tehran
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
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity

Shahid Beheshti University of Medical Sciences, School of Traditional Medicine

Full name of responsible person

Shahpar Kaveh Bagh Bahadorani

Position

PhD candidate

Other areas of specialty/work

Street address

No.8 Shams Alley, Vali-e-Asr Street

City

Tehran

Postal code

Phone

+98 21 8877 6327

Fax

Email

skaveh83@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences, School of Traditional Medicine

Full name of responsible person

Rasool Choopani

Position

Assistant Professor

Other areas of specialty/work

Street address

No.8 Shams Alley, Vali-e-Asr Street

City

Tehran

Postal code

Phone

+98 21 8877 6327

Fax

Email

rchoopani@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences, School of Traditional Medicine

Full name of responsible person

Shahpar Kaveh Bagh Bahadorani

Position

PhD

Other areas of specialty/work

Street address

No.8 Shams Alley, Vali-e-Asr Street

City

Tehran

Postal code

Phone

+98 21 8877 6327

Fax

Email

skaveh83@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty