# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 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**

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## Person responsible for scientific inquiries

**Contact**

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**Position**

Assistant Professor

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## Person responsible for updating data

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**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**

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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*