

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison the effect of Persian medicine products (containing honey and flax seed) and placebo on Forced Expiratory Volume in First Second and wheezing intensity among patients with severe persistent asthma, A triple-blind randomized placebo-controlled trial

#### Protocol summary

##### Study aim

This study aimed to assess the effect of Persian medicine products containing honey and flax seed in patients with severe persistent asthma

##### Design

A randomized controlled clinical trial and triple blind, parallel study

##### Settings and conduct

This study is conducted at Shahid Beheshti Hospital in Qom and the blinding will be done using placebo.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with severe persistent asthma over a year; age group of 12-80. Exclusion criteria: Kidney, liver, and heart failure based on the tests, history and physical exam; High blood pressure more than 180 mm Hg; fever; pregnancy and lactation.

##### Intervention groups

Intervention group: The group will use Persian medicine product (containing honey and flax seed), 40 gram for 3 months, every day. Control group: The group will use placebo, 40 gram every day for 3 months.

##### Main outcome variables

Forced Expiratory Volume in First Second; Wheezing intensity

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170112031893N5**

Registration date: **2019-03-16, 1397/12/25**

Registration timing: **prospective**

Last update: **2019-03-16, 1397/12/25**

Update count: **0**

##### Registration date

2019-03-16, 1397/12/25

##### Registrant information

###### Name

Hossein Yusefi

###### Name of organization / entity

Qom University of medical science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 25 3886 0146

###### Email address

driran1399@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-03-21, 1398/01/01

##### Expected recruitment end date

2020-03-20, 1399/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison the effect of Persian medicine products (containing honey and flax seed) and placebo on Forced Expiratory Volume in First Second and wheezing intensity among patients with severe persistent asthma, A triple-blind randomized placebo-controlled trial

##### Public title

The effect of a Persian medicine product on patients with severe persistent asthma

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with severe persistent asthma over a year Age group 12-80

**Exclusion criteria:**

Kidney,liver,and heart failure based on the tests, history and physical exam High blood pressure more than 180 mm Hg Fever Pergnancy and lactation;

**Age**

From **12 years** old to **80 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients will be randomly allocated into two groups using random numbers table developed by Random Allocation Software.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

In this study, placebo will be used for blinding in which placebo is very similar to the main drug in terms of color and taste. Therefore, patients, statistical analyst and physicians won't be aware of the allocation of patients to either drug or placebo group and someone outside the group is aware of the allocation of treatment.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Qom University of Medical Sciences

**Street address**

Vice chancellor for research of Qom University of

Medical Sciences, Safashar road, Qom, Iran

**City**

Qom

**Province**

Ghous

**Postal code**

87366-37169

**Approval date**

2019-01-29, 1397/11/09

**Ethics committee reference number**

IR.MUQ.REC.1397.177

**Health conditions studied****1****Description of health condition studied**

Asthma

**ICD-10 code**

J45.5

**ICD-10 code description**

Severe persistent asthma

**Primary outcomes****1****Description**

Forced Expiratory Volume in First Second

**Timepoint**

Before and after the intervention (end of month 3)

**Method of measurement**

Spirometry testing

**Secondary outcomes****1****Description**

Wheezing intensity determination

**Timepoint**

At the first of the study(before intervention) and 3 months after intervention

**Method of measurement**

History and physical exam with stethoscope

**Intervention groups****1****Description**

Intervention group: The group will use Persian medicine product (containing honey and flax seed), 40 gram for 3 months, every day.

**Category**

Treatment - Drugs

**2****Description**

Control group: The group will use placebo, 40 gram every

day for 3 months. The placebo contains edible color, aspartame and corn flour, and is made by Tehran University of Medical Sciences.

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Shahid Beheshti hospital

**Full name of responsible person**

Hasan Adeli Nia

**Street address**

Clinical Research Development Center, Shahid Beheshti Hospital, Shahid Beheshti Blvd, Azadegan Sq, Qom, Iran

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Ghous University of Medical Sciences

**Full name of responsible person**

Hossein saghafi

**Street address**

Number 83, Alley 4, Alley 1.1, Safashahr Street

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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**

Ghous 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**

Ghous University of Medical Sciences

**Full name of responsible person**

Hasan Adeli Nia

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pulmonary Medicine

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Ghous University of Medical Sciences

**Full name of responsible person**

Muhammad Hossein Yusefi

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Internal medicine

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Position**

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**Latest degree**

Bachelor

**Other areas of specialty/work**

Internal 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**

With attention to the type of study and publication of the article, there is no need to do this

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not 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