

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jul 2026

### The comparison between Trigonella Foenum- graccum L.( Fenugreek) syrup and honey with placebo in patient with mild asthma

#### Protocol summary

##### Summary

in this study we will comparison between Trigonella foenum- graccum L.( Fenugreek) syrup and honey with placebo in patient with mild asthma which use Ventalex( Salbutamol spray made by Sina Darou) PRN. It is a randomized triple blind study with duration of 4 weeks.Study sample is 90 persons with mild Asthma.At first we complain the study to patient. We will fill demographic information and asthma control questionnaire and some essential lab exams.Also the number of drugs they take in a day and frequency of ashtma attacks will consider. They also asked for Fenugreek and its family sensitivty.Seconded visit will take for spirometry to see probable side effects.Final visit will taken one month after the end of study and we will have spirometry and lab exams and asthma control questionnaire again.When we rich to 90 members the study will be stopped and we will analysis the data.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016011325991N1**

Registration date: **2016-04-02, 1395/01/14**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-04-02, 1395/01/14

##### Registrant information

###### Name

laleh oveidzadeh

###### Name of organization / entity

ardacan school of traditional medicine

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 5237 9254

###### Email address

l\_oveidzadeh@ssu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice Chancellor for research, Shahid Sadoughi University of Medical Sciences

##### Expected recruitment start date

2016-03-20, 1395/01/01

##### Expected recruitment end date

2017-03-21, 1396/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The comparison between Trigonella Foenum- graccum L.( Fenugreek) syrup and honey with placebo in patient with mild asthma

##### Public title

The efficacy of Trigonella Foenum- graccum L. in treatment of mild asthma

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

inclusion criteria: patient with mild asthma in recent year; age between 20 to 60; complete the form; haven't receive any CAM through the study; don't use any aditive fenugreek- haven't sensitivty to fenugreek and certain allergy; don't use MAO Inh drugs; don't have seasonal allergy; not diabetic; don't have an acute disease in heart or liver or kidneys. exclusion crieria: pregnancy or breastfeeding; acute diseases; sensitivty or side effect

of drug; useing anti coagolant drugs; thyroid diseases;  
rihnosinositist; smoking and drug abuse

**Age**

From **20 years** old to **60 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Triple blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features**

The study is triple blind and parallel. The petients inter to the study with simple computeric codes.

**Secondary Ids**

empty

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

Ethics committee of Shahid Sadoughei University of  
Medical Sciences

**Street address**

Bahonar sq. Shahid Saduoghi Medical Science  
University

**City**

Yazd

**Postal code****Approval date**

2015-11-20, 1394/08/29

**Ethics committee reference number**

ir.ssu.rec.1394.130

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

Asthma

**ICD-10 code**

j45.9

**ICD-10 code description**

Asthma

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

spirometry tesr

**Timepoint**

first and second day and a month after study

**Method of measurement**

spirometer

**2****Description**

asthma control test

**Timepoint**

first and a month after study

**Method of measurement**

st. george questionnaire

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

IL4

**Timepoint**

first and a month after study

**Method of measurement**

imunologic test

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

honey syrup for 4 weeks 10 mg bd which made by  
Shahid b Beheshti pharmacy university

**Category**

Treatment - Drugs

**2****Description**

fenugreek syrup for 4 weeks 5mg bd made by Shahid  
Beheshti pharmacy university

**Category**

Treatment - Drugs

**3****Description**

control: suger syrup 5 mg bd for 4 weeks made by  
Shahid Beheshti pharmacy university

**Category**

Placebo

**Recruitment centers****1****Recruitment center**

**Name of recruitment center**  
Tehran Shahid Labafi nezhad Hospital  
**Full name of responsible person**  
Dr. laleh oveidzadeh  
**Street address**  
Pasdaran- Boostan 9th- Shahid Amir Ebrahimi Ave.  
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Tehran

8916978477  
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l\_oveidzadeh@ssu.ac.ir  
**Web page address**

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Vice Chancellor for research, Shahid Sadoughei  
University of Medical Sciences  
**Full name of responsible person**  
Dr. Fatemeh Ezoddini  
**Street address**  
Central department of Shahid Sadoughei Medical  
University, Shahid Bahonar Sq.  
**City**  
Yazd

#### Grant name

-

#### Grant code / Reference number

-

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Vice Chancellor for research, Shahid Sadoughei  
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**  
Faculty of Traditional Medicine, Shahid Sadoughei  
University of Medical Sciences, Ardakan, Yazd  
**Full name of responsible person**  
Dr. laleh oveidzadeh  
**Position**  
PhD student  
**Other areas of specialty/work**  
**Street address**  
Imam Khomeini Ave.  
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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Faculty of Traditional Medicine, Shahid Sadoughei  
University of Medical Sciences, Ardakan, Yazd  
**Full name of responsible person**  
Dr. Majid Emtiazy  
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Professor assistant  
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## Person responsible for updating data

#### Contact

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PhD student  
**Other areas of specialty/work**  
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## 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*