Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 demografic information and asthma control questionnire 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 sensetivity.Seconed visit will take for spirometery to see probable side effects.Final visit will taken one month after the end of study and we will have spirometery 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
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Shahid Sadoughei 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 between20 to 60; complete the form; haven't recive any CAM throgh the study; don't use any adetive fenugreek- haven't sensetivity 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; sensetivity 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

spirometery 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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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
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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

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Person responsible for updating data

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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