Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

The evaluation of the aqueous extract of Malva Sylvesteris, in the treatment of mild to severe adult asthmatic patients in comparison with placebo group; randomized double-blind study

Protocol summary

Summary

The aim of this study is to use the aqueous extract of Malva Sylvestris in the treatment of the adult patients with mild to severe asthma in comparison with a control (placebo) group. This randomized double blind study (neither the patients, nor the researchers will be aware of the treatment and placebo assigned groups) will be conducted over the 100 patients with asthma. Inclusion criteria: age between 15-65 years, minimum 6 months with mild to severe asthma, non-seasonal asthma and non-smoker. Exclusion criteria: respiratory infection, immunologic and neurological disorders, pregnancy, history of myocardial infarction, chronic obstructive pulmonary disorder and diabetes. Using block randomization method, patients will be randomly assigned into two groups (group 1: 600 mg/day aqueous extract of Malva Sylvestris and group 2: placebo) and will be under the treatment for 1 month. The severity and changes in the asthma symptoms will be measured by questionnaire and pulmonary function tests, before, 1 and 3 months after initiation of the treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014082318899N1**
Registration date: **2014-11-30, 1393/09/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-11-30, 1393/09/09

Registrant information

Name

Mojtaba Keshavarz

Name of organization / entity

Bushehr University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Deputy for research of Bushehr University of Medical Sciences

Expected recruitment start date

2014-10-07, 1393/07/15

Expected recruitment end date

2016-10-06, 1395/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of the aqueous extract of Malva Sylvesteris, in the treatment of mild to severe adult asthmatic patients in comparison with placebo group; randomized double-blind study

Public title

The effects of Mallow in the treatment of asthma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 15-65 years, minimum 6 months with mild to severe asthma, non-seasonal

asthma and non-smoker Exclusion criteria: respiratory infection, immunologic and neurological disorders, pregnancy, history of myocardial infarction, chronic obstructive pulmonary disorder and diabetes

Age
From **15 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Bushehr University of Medical Sciences

Street address
Mosala street

City
Bushehr

Postal code

Approval date
2014-06-16, 1393/03/26

Ethics committee reference number
B-93-16-5

Health conditions studied

1

Description of health condition studied
Asthma

ICD-10 code
J45

ICD-10 code description
chronic obstructive asthma

Primary outcomes

1

Description
Forced expiratory volume at first second (FEV1)

Timepoint
Before, 1 month and 3 months after treatment

Method of measurement
Pulmonary function test by spirometry

Secondary outcomes

1

Description
Adverse effects of Malva Sylvestris extract

Timepoint
1 and 3 months after treatment

Method of measurement
Questionnaire and pulmonary function test using spirometry

Intervention groups

1

Description
Intervention 2 in control group: placebo including capsules contain sucrose twice a day for 1 month by oral route

Category
Treatment - Drugs

2

Description
Intervention 1: aqueous extract of Malva Sylvestris at doses of 600 mg/day (300 mg twice a day by oral route for 1 month)

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Bushehr Khalij Fars hospital

Full name of responsible person
Mehrzad Bahtoee

Street address
Mosala Street

City
Bushehr

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy for research of Bushehr University of Medical Sciences
Full name of responsible person
Afshin Ostovar
Street address
Bahmani
City
Busehr
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Deputy for research of Bushehr 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
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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