Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Clinical study of the effect of oral products of three plants: licorice (Glycyrrhiza glabra), fragrant violet (Viola adorata) and tarpaulin (Operculina turpethum) as an add-on on the intervals and severity of moderate chronic asthma attacks in children and adolescents 6 to 18 years

Protocol summary

Study aim

Evaluation of the effectiveness of anti-asthma herbal composition as a therapeutic supplement in the control of moderate chronic asthma in children and adolescents 6 to 18 years.

Design

Clinical trial with control group, one-side blinded, quasi-random based on national code(even or odd), phase 2 on 40 patients

Settings and conduct

The sampling place is Imam Hossein Hospital clinic. All patients aged 6 to 18 years with moderate chronic asthma are sampled. The drug and placebo are exactly the same and differ from the code. the doctor and patients are blinded. The case group takes the main drug and the control group takes placebo; They should eat 4 tablets daily for 1 month. Breathing test is performed before and after taking the drug and a questionnaire to assess the severity of asthma and quality of life before and after the study is completed.

Participants/Inclusion and exclusion criteria

Entry condition: All patients between 6 to 18 years with moderate chronic asthma based on the 2018 Nelson Pediatric Textbook (Page 202) No entry conditions: 1. Simultaneous use of other drugs outside the formal treatment protocol that is effective on the disease. 2. Possible history of underlying cardiovascular, renal, hepatic and biliary tract diseases.

Intervention groups

Both case and control groups will receive standard treatment and in addition to standard treatment, case group will receive herbal product as an adjuvant treatment and control group will receive placebo.

Main outcome variables

Age ; Gender; Number of attacks of shortness of breath per week; Severity of shortness of breath attacks per week; FEV1; FEV1 / FVC; Occurrence of ADR adverse effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090808002306N6**
Registration date: **2021-01-29, 1399/11/10**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-29, 1399/11/10**
Update count: **0**

Registration date

2021-01-29, 1399/11/10

Registrant information

Name

Ali Mohammad Sabzghabaee

Name of organization / entity

Isfahan university of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-06-21, 1400/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical study of the effect of oral products of three plants: licorice (Glycyrrhiza glabra), fragrant violet (Viola adorata) and tarpaulin (Operculina turpethum) as an add-on on the intervals and severity of moderate chronic asthma attacks in children and adolescents 6 to 18 years

Public title

Evaluation of the effect of herbal anti-asthma product along with standard treatment on the intervals and severity of moderate chronic asthma attacks in children and adolescents 6 to 18 years

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients between 6 and 18 years old with chronic asthma in children and adolescents with moderate severity according to the Nelson Pediatrics textbook published in 2018 (page 202) Do not use other drugs at the same time and outside the official treatment protocol that is effective on the disease. No possible history of underlying cardiovascular, renal, hepatic and biliary tract diseases

Exclusion criteria:

Age

From **6 years** old to **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the pulmonologist and patients are not aware of the type of drug received (main drug or placebo). The drug and the placebo are exactly the same and are distinguished only by a small code that only the researcher and responsible for data collection (student) know about.

Placebo

Used

Assignment

Parallel

Other design features

In the design of this study, patients were divided into two categories based on the odd and even national code receiving the main drug (odd national code) and control (even national code). The first group receives anti-asthma drugs and the second group receives placebo that is exactly the same with the main drug; And one month after taking the drug, evaluations are done.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Vice chancellery for research, Isfahan University of Medical Sciences

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2020-12-12, 1399/09/22

Ethics committee reference number

IR.MUI.MED.REC.1399.818

Health conditions studied

1

Description of health condition studied

moderate persistent asthma

ICD-10 code

J45.4

ICD-10 code description

Moderate persistent asthma

Primary outcomes

1

Description

Spiro metric Respiratory Test Index (FEV1).

Timepoint

Spirometry tests are taken from patients before the start of the study and the test is performed again one month after taking the drug.

Method of measurement

Pulmonary indices are recorded by spirometry.

2

Description
Spiro metric Respiratory Test Index (FVC).
Timepoint
Spirometry tests are taken from patients before the start of the study and the test is performed again one month after taking the drug.
Method of measurement
Pulmonary indices are recorded by spirometry.

3

Description
Spiro metric Respiratory Test Index (FEV1/FVC).
Timepoint
Spirometry tests are taken from patients before the start of the study and the test is performed again one month after taking the drug.
Method of measurement
Pulmonary indices are recorded by spirometry.

4

Description
Number of cough attacks per day or week
Timepoint
Before the study and one month after taking the drug
Method of measurement
By asking parents and registering on the data collection form

5

Description
Number of puffs used salbutamol spray per day
Timepoint
Before the study and one month after taking the drug
Method of measurement
By asking parents and registering on the data collection form

6

Description
Severe restrictions on exercise or activity
Timepoint
Before the study and one month after taking the drug
Method of measurement
By asking parents and registering on the data collection form

7

Description
Evaluation of quality of life and asthma control in children and adolescents
Timepoint
Before the study and one month after taking the drug
Method of measurement
Using two asthma control questionnaires completed by parents and children or adolescents.

8

Description
Number of shortness of breath per day or week
Timepoint
Before the study and one month after taking the drug
Method of measurement
By asking parents and registering on the data collection form

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this study, subjects in the case group received 4 packs of 30 anti-asthma pills (containing components: asparagine, hydroxycinnamic acids, glycyrrhizin, salicylic acid, methyl ester, betanitropropionic acid, poline, cycloviolasin, saponins, flavonoids, alkaloids of three plants turbid, aromatic violet and licorice) are delivered. The recipe is two morning pills and two night pills. This herbal compound is produced by Sinafaravar Pharmaceutical Company located in Najafabad, Isfahan.
Category
Treatment - Drugs

2

Description
Control group: The placebo is exactly the same as the main drug produced by Sinafaravar Pharmaceutical Company and is given to the control group for one month with the same prescription.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Children's Hospital
Full name of responsible person
Dr. Mohsen Reisi
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+98 31 3386 8286

Email
emamhossein_hospital@mui.ac.ir
Web page address
http://www.ehuch.mui.ac.ir

2

Recruitment center
Name of recruitment center
Office of Dr. Majid Keyvanfar, Pediatric Lung Specialist
Full name of responsible person
Dr. Majid Keyvanfar
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Sarvieh Building, next to Tohid Public Parking (23 Banafsheh Dead End), Middle Tohid Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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research@mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
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Full name of responsible person
Ali Mohammad Sabzghabaee
Position
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Email

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available