Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A clinical trial comparing the effect of Iris and placebo on clinical symptoms in patients with adult asthma: A double-blind, randomized study

Protocol summary

Study aim

In this research, we investigate the Iris pill's effect on treatment and lung function improvement in adults with asthma.

Design

In a controlled clinical trial, with parallel groups, double-blind, block randomization, patients receive Iris tablets half an hour after each meal or Placebo tablets half an hour after each meal 3 times a day in the experimental and control groups. This study will be phase 3 on 72 patients. Excel software will be used to randomize the list of numbers.

Settings and conduct

Patients with mild to moderate asthma aged 18-60 years, referred to the lung clinic of Luqman Hospital in Tehran, who meet the inclusion criteria, will be selected using a table of random numbers. Patients are divided into two intervention and control groups. The prescribing physician, assistant, and patient will not know any of the contents of the drug and the code will be written on the file (double-blind).

Participants/Inclusion and exclusion criteria

Inclusion criteria: mild to moderate asthma؛ age 18-60; Luqman hospital pulmonary clinic. Non-inclusion criteria: Patients in need of hospitalization; for patients with underlying diseases such as COPD, CF, heart failure, GERD, bronchiectasis, pulmonary embolism, sarcoidosis؛ Smokers; BMI> 29; Pregnant and lactating women

Intervention groups

Intervention group: Iris tablets; Iris tablets half an hour after each meal 3 times a day. Control group: placebo; placebo tablets half an hour after each meal 3 times a day.

Main outcome variables

Shortness of breath; Cough; Wheezing; Sputum; Spray consumption; The backwardness of daily tasks; Rate of waking up early morning due to shortness of breath; Rate of not sleeping at night due to shortness of breath; Chest pain; heaviness in the chest; Full ACT score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200303046677N4**
Registration date: **2021-01-13, 1399/10/24**
Registration timing: **prospective**

Last update: **2021-01-13, 1399/10/24**
Update count: **0**

Registration date

2021-01-13, 1399/10/24

Registrant information

Name

rasool choopani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8877 3521

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-20, 1399/12/30

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial comparing the effect of Iris and placebo on clinical symptoms in patients with adult asthma: A double-blind, randomized study

Public title

The effect of Iris tablet on adult asthma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Slight to moderate asthma Age between 18 to 60 years old

Exclusion criteria:

Severe asthma and requires hospitalization Patients with underlying diseases such as COPD, CHF, heart failure, GERD, bronchiectasis, pulmonary embolism, sarcoidosis Smokers BMI> 29 Pregnant and lactating women

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

A randomization table was created with the Excel software rand option. It was already clear that the process of reading random numbers was from top to bottom. Therefore, 36 random codes were assigned to the drug group and written on the drug, and the next 36 codes were written on the placebo, and the codes were kept confidential for use at the time of conclusion. Then, to create a balance in the number of samples assigned to each of the studied groups, blocking was used by random allocation software, which was able to generate random sequences by blocking method. The size of all the blocks is equal. In this two-group experiment, we will have blocks of size 4 (including 2 people in the intervention group and 2 people in the control group). Blocking is done by a person who is not involved in the study, and the content of the blocks is kept confidential until the end of the study. Randomization unit: individual Randomization tool: Random number table

Blinding (investigator's opinion)

Double blinded

Blinding description

The capsules code will be written to the file. The Prescribing physician, assistant, and patient will not be aware of any capsules content. (Double-blind).

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice-Chancellor in Research Affairs - Shahid Beheshti University of Medical Sciences

Street address

7th Floor; Bldg No.2 ؛ Shahid Beheshti University of Medical Sciences; Arabi Ave; Daneshjoo Blvd; Velenjak

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Postal code

1983963113

Approval date

2020-10-02, 1399/07/11

Ethics committee reference number

IR.SBMU.RETECH.REC.1399.712

Health conditions studied

1

Description of health condition studied

Asthma

ICD-10 code

J45

ICD-10 code description

Asthma

Primary outcomes

1

Description

Shortness of breath

Timepoint

At the beginning of the study; At the end of the fourth and eighth weeks

Method of measurement

Asthma Control Test questionnaire

2

Description

Cough

Timepoint

At the beginning of the study; At the end of the fourth and eighth weeks

Method of measurement

Asthma Control Test questionnaire

3

Description

Wheezing

Timepoint

At the beginning of the study; At the end of the fourth and eighth weeks

Method of measurement

Asthma Control Test questionnaire

4

Description

sputum

Timepoint

At the beginning of the study; At the end of the fourth and eighth weeks

Method of measurement

Asthma Control Test questionnaire

5

Description

Spray consumption

Timepoint

At the beginning of the study; At the end of the fourth and eighth weeks

Method of measurement

Asthma Control Test questionnaire

6

Description

The rate of backwardness from daily tasks

Timepoint

At the beginning of the study. At the end of the fourth and eighth week

Method of measurement

Asthma Control Test questionnaire

7

Description

Rate of waking up early in the morning due to shortness of breath

Timepoint

At the beginning of the study. At the end of the fourth and eighth week

Method of measurement

Asthma Control Test questionnaire

8

Description

The rate of not sleeping at night due to shortness of breath

Timepoint

At the beginning of the study. At the end of the fourth and eighth week

Method of measurement

Asthma Control Test questionnaire

9

Description

Chest pain or tightness

Timepoint

At the beginning of the study; At the end of the fourth and eighth weeks

Method of measurement

Asthma Control Test questionnaire

10

Description

Feeling heavy in the chest

Timepoint

At the beginning of the study; At the end of the fourth and eighth weeks

Method of measurement

Asthma Control Test questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Iris group;8 Kg of Iris root, 2 kg of black pepper, and 2 kg of Valeriana officinalis are ground, 2 kg of Dorema ammoniacum gum is dissolved in vinegar and then filtered and dried in an oven, and the result is ground. The powder obtained from steps 1 and 2 Mix in a ribbon blender with microcrystalline cellulose, povidone, calcium diphosphate calcium, and magnesium stearate for one hour. The powder obtained from step 3 is transferred to the press chamber, and during the direct pressing process, 500 mg tablets are made. Quality control of product components, microbial and fungal tests of components and final product are performed based on valid pharmacopeias and are standard. Is. This pill is standardized based on the number of polyphenols in the product.

Category

Treatment - Drugs

2

Description

Control group: Placebo; The placebo was prepared from corn starch in the same color and size capsules. Placebo was used similarly to the drug used by the intervention group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Loqman haspital

Full name of responsible person
Khosrow Agin

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Loghman Hakim Hospital; Makhsoos street; Lashgar crossroads

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
rasool choopani

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine

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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