Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of PHR160 spray effect on improvement of lung function, asthma severity and exacerbation in severe asthmatic patients.

Protocol summary

Study aim
Determining the effect of PHR160 (Pinen.Hydronoplacton.Ribonucleic acid)spray on improving lung function, severity and asthma attacks in patients with severe asthma

Design
A clinical trial with a control group and a placebo group, parallel, one-sided blind, randomized, the study was conducted on 60 patients and a table of random numbers was used for randomization.

Settings and conduct
The studied patients are selected from among those who refer to the lung clinic of Imam Khomeini Hospital in Ahvaz, Golestan Hospital in Ahvaz, or the personal office of Jundishapour University Pulmonary Doctors in Ahvaz.

Participants/Inclusion and exclusion criteria
including criteria is patients with severe asthma.exclusing criteria is history of reflux, sinusitis, allergic rhinitis, as well as patients with advanced liver and kidney failure, pregnant, or a history of allergy or contraindication to the use of herbal compounds such as menthone, saffron, crocin and Safranel

Intervention groups
Determining the effect of PHR160 spray on improving lung function, severity and asthma attacks in patients with severe asthma

Main outcome variables
FEV1:FVC:FEF25-75:6MWD:Number of asthma attacks

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220610055122N1**
Registration date: **2022-11-01, 1401/08/10**
Registration timing: **registered_while_recruiting**
Last update: **2022-12-16, 1401/09/25**
Update count: **1**

Registration date
2022-11-01, 1401/08/10

Registrant information

Name
hoda mohsenikia

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 4283 1367

Email address
medmosahneh@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-10-24, 1401/08/02

Expected recruitment end date
2022-12-23, 1401/10/02

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of PHR160 spray effect on improvement of lung function, asthma severity and exacerbation in severe asthmatic patients.

Public title
Evaluation of PHR160 spray effect on improvement of severe asthmatic patients.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with severe asthma
Exclusion criteria:
pregnancy history of reflux history of sinusitis History of allergic rhinitis History of advanced liver and kidney failure Allergy and contraindications of herbal compounds such as menthone, saffron, crocin, safranel

Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Using a calculator, random numbers from 1 to 60 were generated, thirty numbers and the first number generated by the calculator were assigned to the intervention group and the next number to the control group, then the package of drugs was assigned from 1 to 60 in order. It was given to the researcher to prescribe to the patients.
Blinding (investigator's opinion)
Double blinded
Blinding description
All sprays were in the same package, a number label was on the spray box. Only the pharmacist was aware of the number assigned to the relevant group. Then, in order from number 1 to 60, the package of drugs was given to the researcher to prescribe to the patients.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Jundi Shapur Ahvaz University of Medical Sciences
Street address
Ahvaz Golestan, Farvardin St., Golestan Hospital
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Approval date
2022-02-01, 1400/11/12
Ethics committee reference number
IR.AJUMS.REC.1400.167

Health conditions studied

1

Description of health condition studied
Severe asthma
ICD-10 code
J45. 998
ICD-10 code description
J45. 998

Primary outcomes

1

Description
Quality of life score (based on quality of life questionnaire in asthmatic patients)
Timepoint
Before the intervention and one month later
Method of measurement
questionnaire

2

Description
The distance covered in the 6-minute walk test (in meters)
Timepoint
Before the intervention and one month later
Method of measurement
6-minute walking test

3

Description
Forced expiratory volume in the first second (FEV1)
Timepoint
Before the intervention and one month later
Method of measurement
spirometry

4

Description
Forced vital capacity (FVC)
Timepoint
Before the intervention and one month later
Method of measurement
spirometry

5

Description
forced expiratory flow 25%-75%

Timepoint
Before the intervention and one month later
Method of measurement
spirometry

6

Description
The number of exacerbations
Timepoint
Before the intervention and one month later
Method of measurement
Calculation of the number of exacerbations of the disease

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: PHR160 spray two puffs every eight hours for one month
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital of Ahvaz
Full name of responsible person
mehrdad dargahi maal amir
Street address
Imam Khomeini Hospital, Azadegan Street, Ahvaz
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Vice President of Research and Technology of Jundishapur University of Medical Sciences, Ahvaz
Street address
Golestan Blvd., University City, Esfand St., Jundishapur University of Medical Sciences, Ahvaz, Vice President of Research and Technology Development
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Email
journal_ajums@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Hoda Mohsenikia
Position
Resident

Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
All personal data of study participants can be shared after de-identification
When the data will become available and for how long
Access starts one month after results are published
To whom data/document is available
There is no access limit for people
Under which criteria data/document could be used
There is no access limit for people
From where data/document is obtainable
Dr. Hoda Mohseni Kia, Ahvaz University of Medical Sciences medmosahneh@gmail.com
What processes are involved for a request to access data/document
Send the request to Dr. Mohseni Kia's email and it will be answered within a month
Comments