Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Effect of Taladafil on Improvement of Lung Function and Asthma Attacks in Patients with Severe Asthma

Protocol summary

Study aim
The Effect of Taladafil on Improving Asthma

Design
Double-blind Randomized Clinical Trial with Control and Parallel Groups

Settings and conduct
20 Patients with Asthma Were Entered into This Study Based on History and Spirometry. The Patients Were Selected from People Who Referred to the Pulmonary Clinic of Imam Khomeini Hospital. Qualified People Were Randomly Divided into Two Groups of 10. Each Group Received High-dose Inhaled Corticosteroids, Long-acting Beta-agonists, Anticholinergic Inhalants and Oral Corticosteroids in a Dose of 5 mg Daily. The First Group Received Taladafil 50 mg daily and the Second Group Received the Same Dose of Placebo. Before Starting the Study, Spirometry, Lung Volume, a Quality of Life Questionnaire and 6MWD Test Were Performed on Patients. After one Month, Spirometry, lung volume, a Quality of Life Questionnaire and 6MWD Test Were Done and Evaluated.

Participants/Inclusion and exclusion criteria
Inclusion criterion: the patients with severe asthma. Exclusion criteria: mild to moderate severity; using immunosuppressive drug and corticosteroid (greater than 5 mg dose); pregnancy; advanced liver or renal failure; any untreated disease and uncontrolled hypertension

Intervention groups
The Patients Were Divided into Groups Receiving Taladafil and Placebo. Intervention Group Received a Single 50 mg Dose of Oral Taladafil (Made in Ahvaz Pharmacy Faculty) Daily during One Month. The Control Group also Received a Single 50 mg Dose of Oral Placebo (Made in Ahvaz Pharmacy Faculty) Daily during One Month.

Main outcome variables
Lung Volumes (Forced expiratory volume in one second); (Forced Vital Capacity) ; (Forced Expiratory flow 25_75 %); Forced Expiratory Volume in 1 Second to Forced Vital Capacity; Quality of Life Score; Walking Distance upon 6 Minute Walking Distance Test

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200823048482N1**
Registration date: **2020-09-09, 1399/06/19**
Registration timing: **prospective**

Last update: **2020-09-09, 1399/06/19**
Update count: **0**

Registration date
2020-09-09, 1399/06/19

Registrant information

Name
Seyed Ali Asghar Fakhr Mousavi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 61 3222 7410

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fakhrmousavi.a@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-10-01, 1399/07/10

Expected recruitment end date
2020-12-30, 1399/10/10

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Taladafil on Improvement of Lung Function and Asthma Attacks in Patients with Severe Asthma

Public title

Evaluating the Effect of Taladafil on the Treatment of Severe Asthma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The Patients with Severe Asthma

Exclusion criteria:

Mild to moderate severity Using Immunosuppressive Drug and Corticosteroid (Greater than 5 mg Dose) Outside the Study Protocol in Three Months Ago Advanced Liver Failure (Liver Cirrhosis), Advanced Renal Failure (CKD Stage 4,5) Pregnancy Uncontrolled Hypertension Havingany Untreated Disease such as Reflux, Sinusitis or Allergic Bronchopulmonary Aspergillosis (ABPA) based on History and Paraclinical Tests which Trigger Asthma Exacerbation Continuously Prohibition of Phosphodiesterase Inhibitors and Nitrate Consumption

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomized Numbers from 1 to 20 Was Produced with a Calculator. The First 10 Numbers Allocated to Intervention Group and the Other 10 Numbers Allocated to Control Group, Then Drug Pockets Sequentially from 1 to 20, Was Given to Researcher for Prescription to Patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

All the Drugs Were in Similar and Dark Pockets, There Was One Numerical Label upon Them. Only Chemist Was Aware from Specific Number that Allocated to Specific Group.Then Drug Pockets Given to Researcher to Prescript and Deliver to Patients, Sequential from 1 to 20.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Jundishapur University of Medical Sciences, Golestan Blvd., Golestan Town

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2020-02-24, 1398/12/05

Ethics committee reference number

IR.AJUMS.REC.1398.920

Health conditions studied

1

Description of health condition studied

Asthma

ICD-10 code

J45

ICD-10 code description

Asthma

Primary outcomes

1

Description

Lung Volume (Forced expiratory volume in one second); (FEV1)

Timepoint

In the First Referral and One Month Later

Method of measurement

Spirometry Test

2

Description

Lung Volume (Forced Vital Capacity); (FVC)

Timepoint

In the First Referral and One Month Later

Method of measurement

Spirometry Test

3

Description
Lung Volume (Forced Expiratory flow 25_75%); (FEF25-75%)
Timepoint
In the First Referral and One Month Later
Method of measurement
Spirometry Test

4

Description
Forced Expiratory Volume in 1 Second to Forced Vital Capacity (FEV1/FVC)
Timepoint
In the First Referral and One Month Later
Method of measurement
Spirometry Test

5

Description
Quality of Life Score (Upon Quality of Life Questionnaire in Asthmatic Patients)
Timepoint
In the First Referral and One Month Later
Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This Group Received a Single 50 mg Dose of Oral Taladafil (Made in Ahvaz Pharmacy faculty) Daily During One Month.
Category
Treatment - Drugs

2

Description
Control group: This Group Received a Single 50 mg Dose of Oral Placebo (Made in Ahvaz Pharmacy Faculty) Daily During One Month.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Pulmonary Clinic of Imam Khomeini Hospital
Full name of responsible person
Ali Asghar Fakhr Mousavi
Street address
Imam Khomeini Hospital, Azadegan Ave
City
Ahvaz
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6193673166
Phone
+98 61 3221 5574
Email
sama.delavari@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Badavi
Street address
Jundishapur University of Medical Sciences, Chancellor for Research and Technology Development, Golestan Blvd., Golestan Town
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6135715794
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info@ajums.ac.ir
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
Seyed Hamid Borsi

Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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Full name of responsible person
Ali Asghar Fakhr Mousavi
Position
Fellowship (sub-specialist assistant)
Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
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Khouzestan
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fakhrmousavi.a@ajums.ac.ir

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
Yes - There is a plan to make this available
Title and more details about the data/document
Information on the main outcome or the like can be shared.
When the data will become available and for how long
Available access 9 months after the publication of results
To whom data/document is available
No
Under which criteria data/document could be used
No
From where data/document is obtainable
Ali Asghar Fakhr Mousavi
What processes are involved for a request to access data/document
Communicate with the responsible person
Comments