

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

Phone

+98 61 3222 7410

Email address

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

Province

Khouzestan

Postal code

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

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 61 3373 8286

Email

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

Street address

Imam Khomeini Hospital., Azadegan Ave

City

Ahvaz

Province

Khouzestan

Postal code

6193673166

Phone

+98 61 3221 5574

Email

borsi-h@ajums.ac.ir

Person responsible for scientific 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

Street address

Imam Khomeini Hospital.,Azadegan Ave

City

Ahvaz

Province

Khouzestan

Postal code

6193673166

Phone

+98 61 3221 5574

Email

borsi-h@ajums.ac.ir

Person responsible for updating data

Contact**Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Ali Asghar Fakhr Mousavi

Position

Fellowship (sub-specialist assistant)

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

Street address

Imam Khomeini Hospital.,Azadegan Ave

City

Ahvaz

Province

Khouzestan

Postal code

6193673166

Phone

+98 61 3221 5574

Email

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