

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

Khuzestan

##### 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**

Khuzestan

#### **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**

Khuzestan

##### **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**

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**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**