Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of sildenafil on improvement of lung function and asthma attacks in patients with severe asthma

Protocol summary

Study aim
The effect of sildenafil 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 sildenafil 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 criteria:The patients with severe asthma. Exclusion criteria: Mild to moderate severity, using immunosuppressive drug and corticosteroid (greater than 5 mg dose), prohibition of phosphodiesterase inhibitors, nitrate consumption, pregnancy, advanced liver or renal failure, any untreated disease, and uncontrolled hypertension.

Intervention groups
The patients were divided into groups receiving sildenafil and placebo. Intervention group received a single 50 mg dose of oral sildenafil (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: **IRCT20140518017738N2**
Registration date: **2019-04-08, 1398/01/19**
Registration timing: **retrospective**

Last update: **2019-04-08, 1398/01/19**
Update count: **0**

Registration date
2019-04-08, 1398/01/19

Registrant information

Name
Mehrdad DargahiMalamir

Name of organization / entity
Ahvaz Jondishapour university of Medical science

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-23, 1397/07/01

Expected recruitment end date
2018-11-22, 1397/09/01

Actual recruitment start date
2018-10-23, 1397/08/01

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of sildenafil on improvement of lung function and asthma attacks in patients with severe asthma

Public title
Evaluating the effect of sildenafil 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 Prohibition of phosphodiesterase inhibitors Nitrate consumption Pregnancy Advanced liver failure (liver cirrhosis) Advanced renal failure (CKD stage 4,5) Having any untreated disease such as reflux, sinusitis or allergic bronchopulmonary aspergillosis (ABPA) based on history and paraclinical tests which trigger asthma exacerbation continuously Uncontrolled hypertension
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **20**
Actual sample size reached: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomized numbers from one to 20 was produced with a calculator, the first ten numbers allocated to intervention group and the other ten 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 one 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
61357-15794
Approval date
2018-09-22, 1397/06/31
Ethics committee reference number
IR.AJUMS.REC.1397.430

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

2

Description
Lung Volume (Forced Vital Capacity); (FVC)
Timepoint
In the first referral and one month later
Method of measurement
spirometry

3

Description
Lung Volume (Forced Expiratory flow 25_75%); (FEF 25-75%)
Timepoint
In the first referral and one month later
Method of measurement
spirometry

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

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

6

Description
walking distance upon 6 minute walking distance test (meter)
Timepoint
In the first referral and one month later
Method of measurement
Six minute walking distance test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This group received a single 50 mg dose of oral sildenafil (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
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
pulmonary clinic of Imam Khomeini hospital
Full name of responsible person
Mehrdad Dargahi Mal Amir
Street address
Imam Khomeini Hospital.,Azadegan Ave
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6193673166
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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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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
Mehrdad Dargahi Male Amir

Position
Pulmonary fellowship

Latest degree
Specialist

Other areas of specialty/work
Internal Medicine

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Imam Khomeini Hospital., Azadegan Ave

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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

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Person responsible for updating data

Contact

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Ahvaz University of Medical Sciences

Full name of responsible person
Mehrdad Dargahi Male Amir

Position
Fellowship (sub-specialist assistant)

Latest degree
Specialist

Other areas of specialty/work
Internal Medicine

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Email
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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
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 6 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
Mehrdad Dargahi Male Amir

What processes are involved for a request to access data/document
Communicate with the responsible person

Comments