

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the sildenafil efficacy in exercise test and spirometric value in CF

Protocol summary

Summary

Purpose: Decrease of respiratory tract inflammation in CF prospective accidental study with 20 patients. Inclusion criteria: Confirmed CF with respiratory; gastrointestinal or urogenital symptom with positive test for CF in two times; (CL>60) male and female more than 8 years with potency of doing spirometry; stable vital sign without upper or lower respiratory tract infection; FEV1>50%. Exclusion criteria: history of sensitivity to sildenafil or daily usage of systemic corticostroid or ibuprofen; LFT>3*normal; biliary cirrhosis; portal hypertention; heart diseases such as aortic stenosis, arrhythmia, coronary artery disaeas; neurological or hematologic or renal disaeas; takingof alfa blocker or nitrate or calcium blocker or CYP3A4 inhibitor such as ketoconazole or erythromycin; history of migraine; druge sensitivity or side effect or no patient inclination to continuation. First the patients do spirometry and FEV1/FVC, FEV1, FEF25-75 are measured then do exercise test for 6 minutes and then use sildenafil. At first 1mg/kg/day in 3 times for one week and then 1mg/kg/dose in 3 times for 3 months, then repeat the same tests. The results will be studied in SPSS18.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016040920175N1**

Registration date: **2016-06-14, 1395/03/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-06-14, 1395/03/25

Registrant information

Name

Mohsen Reisi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Esfahan University of Medical Sciences

Expected recruitment start date

2016-02-21, 1394/12/02

Expected recruitment end date

2016-05-29, 1395/03/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the sildenafil efficacy in exercise test and spirometric value in CF

Public title

The effect of sildenafil in cystic fibrosis disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Confirmed CF with respiratory; gastrointestinal or urogenital symptom with positive test for CF in two times; (CL>60) male and female more than 8 years with potency of doing spirometry; stable vital sign without upper or lower respiratory tract infection; FEV1>50%. Exclusion criteria: History of sensitivity to

sildenafil or daily usage of systemic corticosteroid or ibuprofen; LFT>3*normal; biliary cirrhosis; portal hypertension; heart diseases such as aortic stenosis, arrhythmia, coronary artery diseases; neurological or hematologic or renal diseases; taking of alpha blocker or nitrate or calcium blocker or CYP3A4 inhibitor such as ketoconazole or erythromycin; history of migraine; drug sensitivity or side effect or no patient inclination to continuation.

Age

From **8 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Esfahan University of Medical Sciences

Street address

Hezar-Jerib Street, Darvazeh-Shiraz

City

Esfahan

Postal code**Approval date**

2015-02-18, 1393/11/29

Ethics committee reference number

3946

Health conditions studied**1****Description of health condition studied**

Cystic fibrosis

ICD-10 code

E84

ICD-10 code description

Mucoviscidosis

Primary outcomes**1****Description**

FEV1/FVC

Timepoint

Before the study and 3 months after the start

Method of measurement

Spirometry

2**Description**

FEV1

Timepoint

Before the study and 3 months after the start

Method of measurement

Spirometry

3**Description**

FEF25-75

Timepoint

Before the study and 3 months after the start

Method of measurement

Spirometry

4**Description**

Walking tolerance

Timepoint

Before the study and 3 months after the start

Method of measurement

Minute, ET test

Secondary outcomes**1****Description**

Drug sensitivity

Timepoint

Weekly

Method of measurement

History

Intervention groups**1****Description**

Tablet sildenafil; first: 1mg/kg/day in 3 times for 1 week and then 1mg/kg/dose 3 times in day for 3 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric Medical Center, Imam Hosein hospital

Full name of responsible person

Dr. Zahra Aghaei

Street address

City

Esfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Maryam Pahlevannejad

Street address

Esfahan University of Medical Sciences

City

Esfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Mohsen reisi

Position

Master

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty
Analytic Code
empty

Data Dictionary
empty