

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

evaluation of the effect of gastroesophageal reflux treatment on improving pulmonary function in patients with cystic fibrosis

Protocol summary

Study aim

Determining the effect of gastroesophageal reflux treatment in improving pulmonary function in patients with Cystic Fibrosis

Design

Clinical trial without control group , without blinding , sample size census report, sampling method available

Settings and conduct

The place of operation is Abouzar Ahvaz hospital without blinding. Cystic Fibrosis patients with gastroesophageal reflux (detected by questionnaire) are treated with proton pump inhibitors and spirometry before and after treatment of these patients are compared.

Participants/Inclusion and exclusion criteria

The participants in the study include patients with Cystic Fibrosis who refer to CF clinic of Abouzar hospital who are over 6 years old, do not have severe lung disease , adhere to treatments , and are not treated with proton pump inhibitors.

Intervention groups

We give proton pump inhibitor drugs to cystic fibrosis patients with gastroesophageal reflux

Main outcome variables

Improvement of pulmonary function in Cystic Fibrosis patients with gastroesophageal treated with proton pump inhibitors drugs.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230312057688N1**

Registration date: **2023-05-01, 1402/02/11**

Registration timing: **registered_while_recruiting**

Last update: **2023-05-01, 1402/02/11**

Update count: **0**

Registration date

2023-05-01, 1402/02/11

Registrant information

Name

Elham Pour azar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 918 356 7481

Email address

pourazar-e@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-19, 1402/01/30

Expected recruitment end date

2023-06-20, 1402/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

evaluation of the effect of gastroesophageal reflux treatment on improving pulmonary function in patients with cystic fibrosis

Public title

effect of gastroesophageal reflux treatment in cystic fibrosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Cystic fibrosis patients over 6 years old Not having

advanced respiratory disease
Exclusion criteria:
patients treated with proton pump inhibitors patients
with severe pulmonary disease non adherence to
pulmonary treatments

Age
From **6 years** old

Gender
Both

Phase
2

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

Ethics committee in Golestan Hospital Research

Street address

Golestan Hospital, Golestan Ave.

City

Ahvaz

Province

Khouzestan

Postal code

6135733118

Approval date

2023-01-10, 1401/10/20

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1401.163

Health conditions studied

1

Description of health condition studied

Cystic Fibrosis

ICD-10 code

E84

ICD-10 code description

Cystic fibrosis

Primary outcomes

1

Description

Forced vital capacity

Timepoint

At the begining of the study and 2 months after the intervention

Method of measurement

spirometry

2

Description

Forced effective volume 1 second

Timepoint

At the begining of the study and 2 months after the intervention

Method of measurement

spirometry

3

Description

Forced Effective Volume 25-75

Timepoint

At the begining of the study and 2 months after the intervention

Method of measurement

spirometry

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:cystic fibrosis patients with gastroesophageal reflux are treated with proton pump inhibitors and spirometry is compared before and after the intervention

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Abouzar Hospital

Full name of responsible person

Elham Pourazar

Street address

Abouzar hospital, Tohid Ave. , Pasdaran Blvd.

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pourazar-e@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mehrnoosh Zakerkish
Street address
Golestan Blvd., Ahvaz Jundishapour University Medical Science
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itc@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
Elham pourazar
Position
fellow
Latest degree
Specialist
Other areas of specialty/work
Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Person responsible for updating data

Contact

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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

All data can be shared after de-identifying individuals.

When the data will become available and for how long

Access starts one year after results are published

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

The request to use the data should be sent to the administrator's email , and if approved , the data will be sent.

From where data/document is obtainable

The request to use the data should be sent to the administrator's email , and if approved , the data will be sent. Dr. Mitra Amadi ahmadi_mi@ajums.ac.ir
00989124957050

What processes are involved for a request to access data/document

The request to use the data should be sent to the administrator's email , and if approved , the data will be sent. Dr. Mitra Amadi ahmadi_mi@ajums.ac.ir
00989124957050

Comments