

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The Effect of Cyproheptadine on Growth, Respiratory Status, and Quality of Life in Cystic Fibrosis Patients Aged 6-18 Years

Protocol summary

Study aim

evaluate the effects of cyproheptadine on growth, respiratory status, and quality of life in cystic fibrosis patients

Design

This before and after intervention study is a phase two study in which randomization is not applicable and blinding is not performed, and there is only single study group of 30 cystic fibrosis patients with the main aim of investigating the effect of cyproheptadine on cystic fibrosis patients aged 6 to 18 years.

Settings and conduct

Before and after 6 months of taking 0.25 mg per kilogram of body weight of cyproheptadine divided every 12 hours in cystic fibrosis patients who referred to the clinic of Imam Hossein Hospital in Isfahan, their height, weight and BMI were measured, spirometry was performed for them and a questionnaire related to the quality of life of CF patients was completed. The intervention has only one study group of 30 people and blinding and randomization were not performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: CF, age 6-18 years, and regardless of pancreatic insufficiency or disease severity. Exclusion criteria: known cyproheptadine allergy, intolerance to side effects, or concurrent CNS depressant medication use.

Intervention groups

CF patients diagnosis confirmed via sweat test or genetic testing, age 6-18 years, and regardless of pancreatic insufficiency or disease severity. Participants received cyproheptadine (0.25 mg/kg, q12h) for six months. Growth parameters, pulmonary function (FEV1, FVC), hospitalization frequency, and quality of life were assessed pre- and post-intervention.

Main outcome variables

weight, height, BMI, forced expiratory volume in one second, quality of life, hospitalization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241203063927N1**

Registration date: **2025-09-10, 1404/06/19**

Registration timing: **prospective**

Last update: **2025-09-10, 1404/06/19**

Update count: **0**

Registration date

2025-09-10, 1404/06/19

Registrant information

Name

Marzieh Azizian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 913 687 3189

Email address

azizianmarzieh969@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-23, 1404/07/01

Expected recruitment end date

2026-03-20, 1404/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Cyproheptadine on Growth, Respiratory Status, and Quality of Life in Cystic Fibrosis Patients Aged 6–18 Years	
Public title	Cyproheptadin in cystic fibrosis
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Inclusion criteria were CF diagnosis confirmed via sweat test or genetic testing age 6–18 years and regardless of pancreatic insufficiency or disease severity. Exclusion criteria: known cyproheptadine allergy concurrent CNS depressant medication use
Age	From 6 years old to 18 years old
Gender	Both
Phase	2
Groups that have been masked	No information
Sample size	Target sample size: 30
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	
<u>1</u>	
Ethics committee	
Name of ethics committee	Faculty of Medicine, Isfahan University of Medical Sciences
Street address	Imam Khomeini
City	Esfahan
Province	Isfahan
Postal code	8195163381
Approval date	2023-10-31, 1402/08/09
Ethics committee reference number	IR.MUI.MED.REC.1402.289

Health conditions studied	
<u>1</u>	
Description of health condition studied	Cystic fibrosis
ICD-10 code	E84
ICD-10 code description	E84
Primary outcomes	
<u>1</u>	
Description	Amount of weight gain
Timepoint	Before and after 6 months of use of cyproheptadin
Method of measurement	Scales for weight
Secondary outcomes	
<u>1</u>	
Description	Height increase rate
Timepoint	Before and after 6 months of use of cyproheptadin
Method of measurement	meters for height
<u>2</u>	
Description	Improve respiratory condition
Timepoint	Before and after 6 months of use of cyproheptadin
Method of measurement	Spirometry
<u>3</u>	
Description	quality of life
Timepoint	Before and after 6 months of use of cyproheptadin
Method of measurement	Quality of life questionnaire for cystic fibrosis patients
Intervention groups	
<u>1</u>	
Description	Intervention group: participants received cyproheptadineTehran daro company (0.25 mg/kg, divided q12h) for six months
Category	Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam hossein hospital of esfahan
Full name of responsible person
Marzieh Azizian
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Gholamreza asghari
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81746-73461
Phone
+98 31 3668 8138
Email
research@mui.ac.ir
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
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
Esfahan University of Medical Sciences
Full name of responsible person
Marzieh azizian
Position
Resident
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All data is potentially shareable after de-identification. For example, demographic data and questionnaires and spirometry

When the data will become available and for how long

6 months after the publication of the article

To whom data/document is available

Doctors, university researchers, medical and pharmacy students

Under which criteria data/document could be used

Data from this study are available upon reasonable request from the corresponding author. Access to these data may require the signing of a confidentiality agreement and a written request to the university ethics committee. Analysis of the documentation and data is permitted.

From where data/document is obtainable

Email: marziehazizian969@gmail.com project manager Marzieh Azizian

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

After a written request via email and then consultation with the University Ethics Committee, the requested files will be made available to them within one month

Comments