Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
weihgt,hight,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)

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+98 913 687 3189

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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

1

Ethics committee
Name of ethics committee
Faculty of Medicine, Isfahan University of Medical Sciences
Street address
Imam Khomeini
City
Esfahan
Province
Isfehan
Postal code
8195163381
Approval date
2023-10-31, 1402/08/09
Ethics committee reference number
IR.MUI.MED.REC.1402.289

Health conditions studied

1

Description of health condition studied
Cystic fibrosis
ICD-10 code
E84
ICD-10 code description
E84

Primary outcomes

1

Description
Amount of weight gain
Timepoint
Before and after 6 months of use of cyproheptadin
Method of measurement
Scales for weight

Secondary outcomes

1

Description
Height increase rate
Timepoint
Before and after 6 months of use of cyproheptadin
Method of measurement
meters for height

2

Description
Improve respiratory condition
Timepoint
Before and after 6 months of use of cyproheptadin
Method of measurement
Spirometery

3

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

1

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
Street address
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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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Hezar jerib
City
Esfahan
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Isfehan
Postal code
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
Pediatrics
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Person responsible for scientific inquiries

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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