Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jul 2026

Study the Effectiveness of Outpatient treatment in Cystic Fibrosis Patients in Exacerbation Phase

Protocol summary

Study aim
Study the Effectiveness of Outpatient treatment in Cystic Fibrosis Patients in Exacerbation Phase

Design
Clinical trial without control group

Settings and conduct
This study was conducted at Children Medical Centre (CMC) located in Tehran, Iran. All the eligible patients initially referred to the CMC pulmonary tests center to determining the lung volumes and capacities. After that, the patients were treated, according to accepted therapeutic protocol of CF center of CMC, out patiently for 2 to 4 weeks based on the severity of signs and symptoms. After complement of treatment course, the patients underwent all the previous tests again and data before and after treatment, compared.

Participants/Inclusion and exclusion criteria
Documented diagnosed CF patients older than 6 years who are in exacerbation phase and are also able to perform pulmonary tests physically and mentally

Intervention groups
Outpatient treatment with antibiotics and supportive cares

Main outcome variables
Decrease in airway resistance and lung residual volume and increase in FRV1 and total lung capacity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191112045413N2**
Registration date: **2020-02-14, 1398/11/25**
Registration timing: **retrospective**

Last update: **2020-02-14, 1398/11/25**
Update count: **0**

Registration date
2020-02-14, 1398/11/25

Registrant information
Name
Mehrnaz Olfat
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 7703 7596
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olfat.mehrnaz@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-10-23, 1396/08/01

Expected recruitment end date
2018-04-21, 1397/02/01

Actual recruitment start date
2017-10-23, 1396/08/01

Actual recruitment end date
2018-04-21, 1397/02/01

Trial completion date
2018-04-21, 1397/02/01

Scientific title
Study the Effectiveness of Outpatient treatment in Cystic Fibrosis Patients in Exacerbation Phase

Public title
Study the effectiveness of outpateint treatment of cystic fibrosis exacerbation

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Documented diagnosis of CF Exacerbation phase Older than 6 years

Exclusion criteria:
Patients unable to perform pulmonary tests because of physical or mental limitations

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: **29**
Actual sample size reached: **32**

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 of Tehran University of Medical Sciences

Street address
District 6, Keshavarz Boulevard and Ghods St. crossing. Main Office of Tehran University of Medical Sciences

City
Tehran

Province
Tehran

Postal code
1417653761

Approval date
2018-01-24, 1396/11/04

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1396.4323

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
Percent of patients with increased FEV1 values

Timepoint
Before initiation of outpatient treatment and after completion of treatment

Method of measurement
Spirometry machine

2

Description
Percent of patients with decreased residual volumes of lungs

Timepoint
Before initiation of outpatient treatment and after completion of treatment

Method of measurement
body box (plethysmograph) machines

3

Description
Percent of patients with increased total lung capacities of lungs

Timepoint
Before initiation of outpatient treatment and after completion of treatment

Method of measurement
body box (plethysmograph) machines

4

Description
Percent of patients with decreased airway resistance

Timepoint
Before initiation of outpatient treatment and after completion of treatment

Method of measurement
Impulse oscillometry machine

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Airway clearance therapy by nebulized Hypertonic saline (3, 5 or 7%) and nebulized Ventolin, chest physiotherapy (at least 4 times a day). Oral antibiotic therapy based on sputum and pharyngeal culture, out patiently for 2-4 weeks.Treatment of dehydration and electrolyte corrections by taking oral liquids at home.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Children Medical Center Hospital
Full name of responsible person
Alireza Daneshi Bakhtiar
Street address
No. 62, Mohammad Gharib Street, Keshavarz Blvd.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahraian
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Web page address
http://vcr.tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Reza Modaresi
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
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Person responsible for updating data

Contact

Name of organization / entity
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Mehrnaz Olfat

Position
Pediatric Resident

Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Information of our outcomes will be published

When the data will become available and for how long
6-12 months after publication

To whom data/document is available
Only for academic researchers

Under which criteria data/document could be used
The data of our study will be accessible by other researchers, for doing Meta-analysis.

From where data/document is obtainable
No decision made yet

What processes are involved for a request to access data/document
The researchers should explain the aims of their study. The request will be assessed by our team, and if we agree, the requested data will be emailed.

Comments