Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Evaluating the efficacy of airway clearance therapy (ACT) on short time outcome of cystic fibrosis patients in tabriz chlidren’s hospital

Protocol summary

Study aim

Evaluating the efficacy of airway clearance therapy on short time outcome of CF patients in tabriz chlidren hospital

Design

In this cross-sectional study,patients diagnosed with CF from 21/3/2017 to 21/3/2018, which range from 5to14 years old, and increased lung disease with FEV1=20-70%of the primary hospital admission spirometry will be included in the study and will be randomly divided into three groups

Settings and conduct

Patients in the case group, in addition to antibiotic therapy and conventional chest physiotherapy, were under NIV with BIPAP (NIV on days 2,4 and 6admitted for2 hours) and PEP (on the second day), Fourth and sixth admission for 30 minutes).The control group will be treated with antibiotic therapy and conventional chest physiotherapy. Ultimately, spirometry will be performed once per hospitalization and one day on discharge, and their differences will be compared with FEV1 and FVC The patients under study will be followed up within the next 6 months, and the frequency of exacerbation of the disease, the number of hospital admissions and the length of stay in the hospital will be compared

Participants/Inclusion and exclusion criteria

Inclusion criteria:Patients with CF diagnosis,Patients aged 5 to 14 years,Patients with pulmonary disease with FEV1=20-70% in primary spirometry when admitted Exclusion criteria:Patients with reluctance to continue participating in the study,Patients who can not be traced to a cause such as death, transference to another city,etc.during the study period,Patients who do not have adequate compilation to continue treatment

Intervention groups

in the first and second group(case group),in addition to antibiotic therapy and conventional chest physiotherapy, were under NIV with BIPAP and PEP Fourth and sixth admission for 30minutes)

Main outcome variables

Forced expiratory volume in the first second, FEV1/FVC,peak expiratory flow

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131012014988N3**
Registration date: **2018-04-26, 1397/02/06**
Registration timing: **retrospective**

Last update: **2018-04-26, 1397/02/06**
Update count: **0**

Registration date

2018-04-26, 1397/02/06

Registrant information

Name
Mohammad Barzegar
Name of organization / entity
Pediatric Health Research Center,Tabriz University of Medical Sciences
Country
Iran (Islamic Republic of)
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phrc_mb@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the efficacy of airway clearance therapy (ACT) on short time outcome of cystic fibrosis patients in tabriz chlidren’s hospital

Public title

efficacy of airway clearance therapy (ACT) on short time outcome of cystic fibrosis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

• Patients with CF diagnosis• Patients aged 5 to 14 years• Patients with exacerbation of lung disease with FEV1 = 20-70% in initial spirometry when admitted

Exclusion criteria:

• Patients with reluctance to continue participating in the study• Patients who can not be traced to a cause such as death, transference to another city, etc. during the study period.• Patients who do not have adequate compilation to continue treatment.

Age

From **5 years** old to **14 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Regional Ethics Committee, Office of the Vice Chancellor for Research, Tabriz University of Medical

Street address

تبریز-خیابان دانشگاه-ساختمان مرکزی شماره 2 دانشگاه علوم پزشکی تبریز- طبقه سوم-معاونت تحقیقات و فن آوری دانشگاه علوم پزشکی تبریز

City

tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2017-12-04, 1396/09/13

Ethics committee reference number

IR.TBZMED.REC.1396.827

Health conditions studied

1

Description of health condition studied

cystic fibrosis

ICD-10 code

E84.0

ICD-10 code description

Cystic fibrosis with pulmonary manifestations

Primary outcomes

1

Description

Forced expiratory volume in the first second

Timepoint

In the second and last day of the admission

Method of measurement

By using spirometry device

2

Description

FEV1/FVC

Timepoint

In the second and last day of the admission

Method of measurement

By using spirometry device

3

Description

peak expiratory flow

Timepoint

In the second and last day of the admission

Method of measurement

By using peak flow-meter device

Secondary outcomes

1

Description

Number of Exacerebration within six months

Timepoint

within six months

Method of measurement
Cheklist

Intervention groups

1

Description
Intervention group: In addition to antibiotic therapy and conventional chest physiotherapy, patients underwent NIV with BIPAP (NIV on days 2, 4 and 6 admitted for 2 hours) and PEP (on the second, fourth and sixth days on admission for 30 minutes) Placed
Category
Treatment - Other

2

Description
Control group: The control group will be treated with antibiotics and conventional chest physiotherapy only. Ultimately, spirometry will be performed once per hospitalization and one day on discharge, and their differences will be compared with FEV1 and FVC.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz children hospital
Full name of responsible person
Nemat Bilan
Street address
خیابان ششگلان- مرکز آموزشی و درمانی کودکان
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Reasearch Deputy, Tabriz University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Reasearch Deputy, Tabriz 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
Pediatric Health Research Center, Tabriz University of Medical Sciences
Full name of responsible person
Nemat Bilan
Position
Pediatric pediatric pulmonologist, Professor, Faculty Member
Latest degree
Subspecialist
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)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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