

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

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

Protocol summary

Study aim

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

Design

In this cross-sectional study, patients diagnosed with CF from 21/3/2017 to 21/3/2018, which range from 5 to 14 years old, and increased lung disease with $FEV_1 = 20-70\%$ 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 6 admitted for 2 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 FEV_1 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 $FEV_1 = 20-70\%$ 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 30 minutes)

Main outcome variables

Forced expiratory volume in the first second, FEV_1/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)

Phone

+98 41 3526 2265

Email address

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 children'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 Exacerbation within six months

Timepoint

within six months

Method of measurement

Cheklst

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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phrc_mb@tbzmed.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Reasearch Deputy, Tabriz University of Medical Sciences

Full name of responsible person

Abolgasem Jouyban

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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

Pediatrics

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Pediatric Health Research Center, Children Hospital, Sheshgelan street, Tabriz, Iran.

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Email

Person responsible for scientific inquiries

Contact

Name of organization / entity

Pediatric Health Research Center, Tabriz University of Medical Sciences

Full name of responsible person

Nemat Bilan

Position

Pediatric Pulmonologist

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

Contact

Name of organization / entity

Tabriz Children Hospital

Full name of responsible person

Masoomah Ghasemour

Position

Pediatric pulmonary fellowship

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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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