Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

Effects of pulmonary rehabilitation in adult patients with cystic fibrosis - a clinical intervention

Protocol summary

Study aim
The purpose of this study was to evaluate the impact of pulmonary rehabilitation on the general health of patients with CF that are already in treatment with CF transmembrane conductance regulator (CFTR) modulators

Design
An interventional study of 28 patients who performed pulmonary rehabilitation for 3 weeks

Settings and conduct
The study was performed at a single pulmonary rehabilitation center in Timisoara, Romania. Patients received for 3 weeks pulmonary rehabilitation

Participants/Inclusion and exclusion criteria
Inclusion criteria were patients confirmed with CF after medical consultation, age > 18 years, sweat test (iontophoresis), genetic testing, and non-smokers. Furthermore, it was imperative to ascertain the current therapy status involving CFTR modulators. Exclusion criteria were: age < 18 years, exacerbations in the last month, patients with active smoking status, and other lung diseases than CF.

Intervention groups
The intervention group received for 21 days, daily training sessions that lasted between 30 and 40 minutes and included diaphragmatic breathing, pursed-lip breathing, strength and endurance training for both the upper and lower extremities, respiratory muscle training, and clearance techniques

Main outcome variables
The quality of life assessed with the CFQ-R questionnaire improved significantly.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231115060065N2**

Registration date: **2023-12-05, 1402/09/14**

Registration timing: **retrospective**

Last update: **2023-12-05, 1402/09/14**

Update count: **0**

Registration date

2023-12-05, 1402/09/14

Registrant information

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Alexandru Florian Crișan

Name of organization / entity
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Romania

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-30, 1402/03/09

Expected recruitment end date

2023-11-12, 1402/08/21

Actual recruitment start date

2023-06-02, 1402/03/12

Actual recruitment end date

2023-11-12, 1402/08/21

Trial completion date

2023-11-12, 1402/08/21

Scientific title

Effects of pulmonary rehabilitation in adult patients with cystic fibrosis - a clinical intervention

Public title

Pulmonary rehabilitation in patients with cystic fibrosis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients confirmed with cystic fibrosis after medical consultation Age > 18 years Non-smokers status

Exclusion criteria:
Age < 18 years Exacerbations in the last month Other lung diseases than cystic fibrosis

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**
Actual sample size reached: **28**

Randomization (investigator's opinion)
Not randomized

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
Comisia de Etică a Spitalului de Boli Infectioase si Pneumoftiziologie Victor Babes Timisoara

Street address
Gheorghe Adam nr. 13

City
Timisoara

Postal code
300310

Approval date
2023-05-30, 1402/03/09

Ethics committee reference number
4989

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
CFQ-R questionnaire domains will improve

Timepoint
Before intervention and 3 weeks after intervention.

Method of measurement
CFQ-R.

Secondary outcomes

1

Description
Physical capacity will improve

Timepoint
before intervention and 3 weeks after intervention

Method of measurement
6MWT

2

Description
Respiratory muscle strength will improve

Timepoint
before intervention and 3 weeks after intervention

Method of measurement
MIP/MEP

Intervention groups

1

Description
Intervention group: received for 21 days, daily training sessions that lasted between 30 and 40 minutes and included diaphragmatic breathing, pursed-lip breathing, strength and endurance training for both the upper and lower extremities, respiratory muscle training, and clearance techniques

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Clinical Hospital of Infectious Diseases and Pulmonology, Victor Babes Timisoara, Romania

Full name of responsible person
Pescaru Camelia Corina

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
University of Medicine and Pharmacy Victor Babes Timisoara
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
University of Medicine and Pharmacy Victor Babes Timisoara
Full name of responsible person
Pesacaru Camelia Corina
Position
Lecturer
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Not 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
No - There is not 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