

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 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

Name

Alexandru Florian Crişan

Name of organization / entity

University of Medicine and Pharmacy Victor Babes
Timisoara

Country

Romania

Phone

+40 765 525 688

Email address

crisan@umft.ro

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

Street address
Gheorghe Adam nr. 13
City
Timisoara
Postal code
300310
Phone
+40 722 818 228
Email
pescaru.camelia@umft.ro

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
University of Medicine and Pharmacy Victor Babes
Timisoara
Full name of responsible person
Pescaru Camelia Corina
Street address
Eftimie Murgu
City
Timisoara
Postal code
300041
Phone
+40 722 818 228
Email
pescaru.camelia@umft.ro
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

Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
Eftimie Murgu
City
Timisoara
Province
Timis
Postal code
300041
Phone
+40 722 818 228
Email
pescaru.camelia@umft.ro

Person responsible for scientific inquiries

Contact

Name of organization / entity
University of Medicine and Pharmacy Victor Babes
Timisoara
Full name of responsible person
Pescaru Camelia Corina
Position
Lecturer
Latest degree
Ph.D.
Other areas of specialty/work
Pneumology
Street address
Eftimie Murgu
City
Timisoara
Province
Timis
Postal code
300041
Phone
+40 722 818 228
Email
pescaru.camelia@umft.ro

Person responsible for updating data

Contact

Name of organization / entity
University of Medicine and Pharmacy Victor Babes
Timisoara
Full name of responsible person
Pescaru Camelia Corina
Position
Lecturer
Latest degree
Ph.D.
Other areas of specialty/work
Pneumology
Street address
Eftimie Murgu
City
Timisoara

Province

Timis

Postal code

300041

Phone

+40 722 818 228

Email

pescaru.camelia@umft.ro

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