Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Efficacy of using oscillatory-PEP device on pulmonary function based on spirometry indices in patient with cystic fibrosis (Randomized control trial)

Protocol summary

Study aim

Improving pulmonary function based on spirometry indicators in patients with cystic fibrosis using a vibrating positive pressure device (floater)

Design

A controlled, parallel-group, double-blind, randomized clinical trial on 90 patients using web-based randomization.

Settings and conduct

90 patients will be selected based on the inclusion criteria among outpatients diagnosed with cystic fibrosis referring to Akbar hospital clinic in Mashhad. The evaluators and analysts are unaware of the allocation of the study groups. In a group (control), there will be breathing physiotherapy in the traditional form by percussion and vibration method, 3 times a day and each time for 15 minutes, and in the group receiving physiotherapy with a floater (intervention), in addition to 3 sessions of physiotherapy, 3 sessions Flutter will also be done and finally the lung function will be evaluated through spirometry.

Participants/Inclusion and exclusion criteria

Cystic fibrosis patients must have clinical symptoms of the disease and the sweat test indicates the disease. Also, patients should be able to perform the spirometry maneuver and FEV1 should be more than 30% of normal based on age, gender and height. Oxygen saturation should be greater than or equal to 90% and the disease should also be clinically stable. and exclussion criteria contain hemoptysis, pneumothorax, acute respiratory diseases.

Intervention groups

In the control group, there will be breathing physiotherapy in the traditional form by percussion and vibration method, which will be 3 times a day and each time for 15 minutes, and in the intervention group, in addition to receiving 3 times, 3 times of floater between morning and noon, between There will be a shift in the afternoon and evening and a shift at the end of the night.

Main outcome variables

expiratory fluctuating positive pressure, cystic fibrosis, lung function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101107005123N4**
Registration date: **2024-02-25, 1402/12/06**
Registration timing: **registered_while_recruiting**

Last update: **2024-02-25, 1402/12/06**
Update count: **0**

Registration date

2024-02-25, 1402/12/06

Registrant information

Name

Hamidreza Kianifar

Name of organization / entity

Mashahd University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-18, 1402/09/27

Expected recruitment end date

2024-12-17, 1403/09/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of using oscillatory-PEP device on pulmonary function based on spirometry indices in patient with cystic fibrosis (Randomized control trial)

Public title

Efficacy of using oscillatory-PEP device on pulmonary function based on spirometry indices in patient with cystic fibrosis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Cystic fibrosis patients who have been diagnosed based on clinical symptoms and sweat test and have referred to the clinic or office as an outpatient Entry age is above 5 years The percentage of oxygen saturation based on pulse oximetry should be greater than or equal to 90% at room temperature Be clinically stable Able to perform the spirometry maneuver and have a minimum FEV1 greater than or equal to 30% based on the normal population based on age, gender and height Informed consent has been obtained from the patients

Exclusion criteria:

Have evidence of severe complications of lung disease including severe hemoptysis or pneumothorax within the last 2 months Have an acute upper respiratory disease

Age

From **5 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method and description of each method: simple randomization Randomization Unit: Individual Randomization tool: table of random numbers Patients are divided into intervention and control groups based on a simple random allocation method (using a table of random numbers through a computer), and people are randomly assigned to one of the intervention and placebo groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind study, the evaluator and the analysts are unaware of each person participating in the study in the main intervention group (use of floater) or control (not using floater). For blinding, the assigned codes are written separately on separate sheets and placed inside separate envelopes, and the sheets are folded in such a way that the number written inside cannot be seen. After the visit of each patient who meets the entry criteria, an envelope is removed and according to the number written in it, the patient is placed in one of the two groups, A or B.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Medicine-Mashhad University of Medical Sciences

Street address

Nutrition Department, School of Medicine, East door of Ferdowsi University, Azadi Sq.

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2022-05-31, 1401/03/10

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1401.207

Health conditions studied

1

Description of health condition studied

Cystic fibrosis

ICD-10 code

E84.9

ICD-10 code description

Cystic fibrosis, unspecified

Primary outcomes

1

Description

Forced expiratory volume1 (FEV1)

Timepoint

At the beginning of the study and 4 weeks after the intervention

Method of measurement
CHESTGRAPH HI-105 spirometer device

Secondary outcomes

1

Description
Forced vital capacity (FVC)
Timepoint
At the beginning of the study and 4 weeks after the intervention
Method of measurement
CHESTGRAPH HI-105 spirometer device

2

Description
Forced expiratory flow 25–75 (FEF25-75%)
Timepoint
At the beginning of the study and 4 weeks after the intervention
Method of measurement
CHESTGRAPH HI-105 spirometer device

Intervention groups

1

Description
Intervention group: In the group receiving physiotherapy with floater (intervention), in addition to 3 sessions of physiotherapy, 3 sessions of floater will be performed between morning and noon, between noon and evening and one session at the end of the night.
Category
Rehabilitation

2

Description
Control group: In the control group, there will be breathing physiotherapy in the traditional form by percussion and vibration method, which will be 3 times a day and each time for 15 minutes.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Akbar Children's Hospital
Full name of responsible person
Hamidreza Kianifar
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Namaz Blvd., Zakaria Land., Akbar Children hospital., Mashhad Town
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Taskheti
Street address
University Vice-Chancellor for Research and Technology., 3rd Floor.,University of Medical Sciences., Next to Hoize Cinema., University Stree.,Mashhad., Khorasan Razavi
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Saeedeh Talebi
Position
Professor
Latest degree

Ph.D.

Other areas of specialty/work
Nutrition

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is 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

Title and more details about the data/document
Individually nonidentifiable data of participants will be shared in this study. also, the protocol, results, and statistical analysis of the study will be published in the relevant articles.

When the data will become available and for how long
Access to data begins 6 months after publication of results.

To whom data/document is available
The unidentifiable personal data of the participants will be made available to other researchers at academic institutions.

Under which criteria data/document could be used
The unidentifiable personal data of the participants can only be used for research.

From where data/document is obtainable
Individually nonidentifiable information of participants can be obtained by sending an email to Dr. Saeedeh Talebi (TalebiS@mums.ac.ir)

What processes are involved for a request to access data/document
Other researchers in academic institutions can send their requests by email to Dr. Saeedeh Talebi. The data will be sent to them after consulting and approving the research team.

Comments