ISRCTN13019180 https://doi.org/10.1186/ISRCTN13019180

Pulmonary rehabilitation in COPD and interstitial lung diseases

Submission date	Recruitment status	[_] Prospectively registered
19/12/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/01/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/02/2025	Respiratory	

Plain English summary of protocol

Background and study aims
Chronic Obstructive Pulmonary Disease (COPD) and Interstitial Lung diseases (ILD) are terms to describe lung diseases that can cause breathing problems. Pulmonary rehabilitation is a programme of exercise, education and support to help those with COPD and/or ILD to breathe and function. The aim of this study is to examine the effectiveness of pulmonary rehabilitation on function, systemic and oxidative stress markers and the quality of life of patients with COPD and/or ILD.

Who can participate?
Patients aged 30 to 80 with COPD or ILD

What does the study involve?
The pulmonary rehabilitation programme includes breathing training and controlled breathing techniques for 30 minutes in the morning as well as a personalised training program 2-3 times per day for 10-30 minutes using cycling and a treadmill in a format of continuous or interval training. The duration of the rehabilitation program is three weeks. All patients undergo tests including lung function testing and quality of life assessments at the start and the end of rehabilitation and after 6 and 12 months.

What are the possible benefits and risks of participating?
The possible benefits for patients participating in this study are improvement in heart and lung condition. The study is supervised by medical doctors, specialists and physiotherapists and there is a complete health check before participating. The program is absolutely safe for the patients.

Where is the study run from?
1. National Koranyi Institute for Pulmonology (Hungary)
2. Semmelweis University (Hungary)

When is the study starting and how long is it expected to run for?
July 2012 to December 2023

Who is funding the study?
National Koranyi Institute for Pulmonology (Hungary)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
25/2017

Study information

Scientific Title
The effectiveness of pulmonary rehabilitation in COPD and interstitial lung diseases

Acronym
PULMREHABCOPDILD

Study objectives
What is the effectiveness of pulmonary rehabilitation on functional parameters, quality of life and systemic, oxidative stress parameters in COPD and ILD?

Ethics approval required
Old ethics approval format

Ethics approval(s)

Ethics Committee of the National Koranyi Institute for Pulmonology, 17/11/2017, ref: 25/2017

Study design
Observational cross-sectional cohort single-centre study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
COPD, interstitial lung diseases with or without pulmonary hypertension

Interventions
This study tests the effectiveness of pulmonary rehabilitation on chest kinematics, lung mechanics, lung function, metabolism, peripheral and respiratory muscle function, exercise physiology and systemic effect. The pulmonary rehabilitation programme includes breathing training and controlled breathing techniques for 30 minutes in the morning as well as a personalised training program 2-3 times per day for 10-30 minutes using a cycling and treadmill in a format of continuous or interval training.

Pulmonary function programme includes the following:
According to ATS/ERS guidelines all patients underwent post-bronchodilator pulmonary function testing (Vmax 229 and Autobox 6200, Sensormedics) including spirometry measurements. COPD patients inhaled 400 g salbutamol 20 minutes before testing.

Functional follow-up and quality of life questionnaire
Functional follow-up included complex assessment, measurement of lung functions, chest wall expansion, six minutes walking test (6MWT) and quality of life tests such as COPD Assessment Test (CAT) and Modified Medical Research Council Dyspnoea Scale (MMRC).

Personalized training programs
The pulmonary rehabilitation programme includes 30 minutes of respiratory training in the morning, chest wall mobilisation, learning the controlled breathing techniques, inhalation, expectoration, improving the psychological condition, smoking cessation and a personalized training. Patients participate in an individualized continuous or interval type of cycle- and/or treadmill training for 10-30 minutes, two-three times a day at a level of 60-80% of maximal intensity. The duration of the rehabilitation program is three weeks. The intensity of the training is progressive from 60-80% of peak work rate, the intensity was increased based on maintaining Borg dyspnoea scale breathlessness and leg fatigue both on grade No 7.

Systemic and oxidative stress markers
IL-6 and TNF-alfa in cytokines and malondialdehide and isoprostane-8 are measured before and after the rehabilitation and the observational period.

Smoking cessation
Smoking cessation is an important part of the perioperative rehabilitation program. Our institute has a special smoking cessation program for the patients once per week for 45 minutes, with help of psychologists.

The plan is to measure the above functional, systemic and quality of life markers at start of the rehabilitation and end of the rehabilitation. The functional and quality of life parameters and tumor biological response are measured 6 and 12 months after the rehabilitation.

Intervention Type
Mixed

Primary outcome measure
1. Lung function is measured using spirometry at end of rehabilitation and at 6 and 12 months
2. Oxygen uptake is measured using the cardiopulmonary exercise test at the end of the rehabilitation and at 6 and 12 months
3. Metabolism at the end of the rehabilitation is measured using the cardiopulmonary exercise test at the end of the rehabilitation and at 6 and 12 months
4. Systemic inflammation is measured by routine laboratory methods for hsCRP, ELISA for cytokines, sputum and plasma concentration with HPLC at the end of rehabilitation, 6 and 12 months
5. Oxidative stress is measured by enzyme immunoassay techniques at the end of rehabilitation, 6 and 12 months

Secondary outcome measures
1. Chest kinematics is measured using thoracic circumference at the end of the rehabilitation and at 6 and 12 months
2. Lung mechanics is measured using lung function at the end of the rehabilitation and at 6 and 12 months
3. Peripheral and respiratory muscle function is measured using grip strength and peripheral muscle force measurement at the end of the rehabilitation and at 6 and 12 months
4. Quality of life is measured using CAT marker and mMRC at the end of the rehabilitation and at 6 and 12 months

Overall study start date
01/07/2012

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Patients with COPD or interstitial lung disease
2. Age between 30 and 80 years
3. Able to perform respiratory training and endurance training

4. Able to understand the meaning of the program
5. Without significant psychological disease, which has influence the outcome of the rehabilitation

Participant type(s)
Patient

Age group
Mixed

Lower age limit
30 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
500 patients with COPD or interstitial lung disease

Key exclusion criteria
1. Not able to perform the pulmonary rehabilitation program because of joint disease
1. Not able to perform the pulmonary rehabilitation program because of psychological disorder

Date of first enrolment
18/11/2017

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
Hungary

Study participating centre
National Koranyi Institute for Pulmonology
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Study participating centre
Semmelweis University
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Sponsor type
Government

ROR
https://ror.org/051mrhb02

Funder(s)

Funder type
Government

Funder Name
National Koranyi Institute for Pulmonology

Results and Publications

Publication and dissemination plan
The trialists are planning papers in Hungarian and international conferences on this topic and to publish at least three publications in this field. The publications are planned to publish when the data are available. They plan to publish the first data in February/March 2018 and would like to have at least 3-4 publications by 31/12/2024.

Intention to publish date
01/03/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Janos T. Varga (janosvargaster@gmail.com). The data of the study will be available before publication until the end of the study. The data can be shared as a cooperative collaboration for meta-analysis after publication. All of the participants gave a written consent form and the data are anonymous.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/10/2021	21/10/2021	Yes	No
Results article		14/09/2022	29/09/2022	Yes	No
Results article		20/01/2023	05/02/2025	Yes	No
Results article		01/08/2020	05/02/2025	Yes	No
Results article		01/12/2018	05/02/2025	Yes	No
Results article		03/09/2021	05/02/2025	Yes	No