# Pulmonary rehabilitation in COPD and interstitial lung diseases

<b>Submission date</b> 19/12/2017	Recruitment status No longer recruiting	<ul> <li>Prospectively registered</li> </ul>		
19/12/2017		Protocol		
<b>Registration date</b> 16/01/2018	Overall study status Completed	Statistical analysis plan		
		[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?
Dr Janos Varga
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# Contact information

### Type(s)

Scientific

#### Contact name

Dr Janos Tamas Varga

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# Additional identifiers

## Protocol serial number

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

# Study type(s)

Quality of life

### 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

### Primary outcome(s)

- 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

### Key secondary outcome(s))

- 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

### 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

# Healthy volunteers allowed

No

### Age group

Mixed

### Lower age limit

30 years

### Upper age limit

### Sex

All

# 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

No 1, Piheno Street Budapest Hungary 1121

# Study participating centre Semmelweis University

No 26, Ulloi Street Budapest Hungary H-1086

# Sponsor information

### Organisation

National Koranyi Institute for Pulmonology

### **ROR**

https://ror.org/051mrhb02

# Funder(s)

## Funder type

Government

### **Funder Name**

National Koranyi Institute for Pulmonology

# **Results and Publications**

# 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes