

# Perioperative pulmonary rehabilitation in thoracic surgery

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<b>Registration date</b> 06/11/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 07/03/2024	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Chronic Obstructive Pulmonary Disease (COPD) is a term to describe lung diseases that can cause breathing problems. Pulmonary rehabilitation is a programme of exercise, education and support to help those with COPD be able to breathe and function. It is important for patients with COPD be able to function, especially if they are undergoing operations for their lung cancer or other respiratory diseases. The aim of the study is to examine the effectiveness of pulmonary rehabilitation on function, quality of life and tumours in patients with COPD.

### Who can participate?

Patients aged 30 to 80 years old with COPD.

### What does the study involve?

Participants undergo a pulmonary rehabilitation programme. This includes breathing training as well as practice 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. Participants are followed up at six and 12 months to assess their lung function, oxygen uptake, metabolism, complications and tumour response.

### What are the possible benefits and risks of participating?

Participants may experience a positive effect on their cardiovascular system. There are no direct risks with participating in this study.

### 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?

June 2016 to December 2020

### Who is funding the study?

National Koranyi Institute for Pulmonology (Hungary)

Who is the main contact?  
Dr Janos Tamasa Varga

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Janos Tamas Varga

**Contact details**  
National Koranyi Institute for Pulmonology  
No 1, Pihenó Street  
Budapest  
Hungary  
1121  
+36 208 081088  
janosvargaster@gmail.com

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
EB 36/2016

## Study information

**Scientific Title**  
The effectiveness of pulmonary rehabilitation on functional and quality of life parameters and tumor biological response in the PERIOPREPULMHAB study

**Acronym**  
PERIOPREPULMHAB

**Study objectives**  
What is the effectiveness of pulmonary rehabilitation on functional parameters, quality of life and tumour biology?

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
Scientific Ethical Committee of the National Koranyi Institute, 30/11/2016, ref. No: 36/2016

**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 contact details to request a participant information sheet

**Health condition(s) or problem(s) studied**

Lung cancer, lung abscess, COPD, interstitial lung disease, tuberculosis

**Interventions**

This study tests the effectiveness of pulmonary rehabilitation on chest kinematics, lung mechanics, lung function, metabolism, peripheral and respiratory muscle function, exercise physiology, tumor biology. 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.

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 (6MWD) 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 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.

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 measuring the above functional and quality of life markers at start of the rehabilitation and end of the rehabilitation. and detecting the postoperative surgical complications in two weeks after thoracic operation. The functional and quality of life parameters and tumor biological response are measured six and 12 months after the operations.

### **Intervention Type**

Procedure/Surgery

### **Primary outcome measure**

1. Improvement of lung function is measured using spirometry the at end of rehabilitation and six and 12 months after the operation
2. Oxygen uptake is measured using the cardiopulmonary exercise test at the end of the rehabilitation and at 6 and 12 months after the operation
3. Metabolism at the end of the rehabilitation is measured using the cardiopulmonary exercise test at the end of the rehabilitation and at six and 12 months after the operation
4. Complications of the thoracic operation at 2 weeks after the thoracic surgery can be observed and at six and 12 months after the operation
5. Tumor biological response is measured using different analytical methods at six and 12 months after the operation

### **Secondary outcome measures**

1. Chest kinematics is measured using thoracic circumference at the end of the rehabilitation and at 6 and 12 months after the operation
2. Lung mechanics is measured using lung function at the end of the rehabilitation and at 6 and 12 months after the operation
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 after the operation
4. Quality of life is measured using CAT marker and mMRC at the end of the rehabilitation and at 6 and 12 months after the operation

### **Overall study start date**

01/07/2012

### **Completion date**

01/12/2023

## **Eligibility**

### **Key inclusion criteria**

1. Patients with COPD or interstitial lung disease
2.  $30 < \text{Age} < 80$  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

**Sex**

Both

**Target number of participants**

450 patients, 3 clusters, 150 patients in all cluster

**Key exclusion criteria**

1. Inoperable lung cancer because of oncological staging
2. Not able to perform the pulmonary rehabilitation program because of joint disease
3. Not able to perform the pulmonary rehabilitation program because of psychological disorder

**Date of first enrolment**

30/11/2016

**Date of final enrolment**

30/11/2022

## **Locations**

**Countries of recruitment**

Hungary

**Study participating centre**

**National Koranyi Institute for Pulmonology**

No 1, Pihenó Street

Budapest

Hungary

1121

**Study participating centre**

**Semmelweis University**

Budapest, Üllői út 26

Budapest

Hungary

1085

## **Sponsor information**

**Organisation**

National Koranyi Institute for Pulmonology

**Sponsor details**

No 1, Piheno Street

Budapest

Hungary

1121

+36 208 081088

varga@koranyi.hu

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/051mrhb02>

**Funder(s)****Funder type**

University/education

**Funder Name**

National Koranyi Institute for Pulmonology

**Results and Publications****Publication and dissemination plan**

We are planing to have papers in Hungarian and international conferences in this topic and publish at least 3 publication in this field. The publications are planed to publish when the data are available. The date of the first planed publication is 04/2017.

**Intention to publish date**

28/04/2017

**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](mailto:janosvargaster@gmail.com)

**IPD sharing plan summary**

Available on request