ISRCTN97596271 https://doi.org/10.1186/ISRCTN97596271

Perioperative pulmonary rehabilitation in thoracic surgery

Submission date	Recruitment status	[_] Prospectively registered
29/10/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/11/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/02/2026	Respiratory	

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, Piheno Street
Budapest
Hungary
1121
+36 208 081088
janosvargaster@gmail.com

Additional identifiers

Protocol serial number
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

Study type(s)
Quality of life

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, peripherial 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(s)
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

Key secondary outcome(s))
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 peripherial 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

Completion date
01/12/2023

Eligibility

Key inclusion criteria
1. Patients with COPD or interstitial lung disease
2. 30<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

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
238

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, Piheno Street
Budapest
Hungary
1121

Study participating centre
Semmelweis University
Budapest, Üllői út 26
Budapest
Hungary
1085

Sponsor information

Organisation
National Koranyi Institute for Pulmonology

ROR
https://ror.org/051mrhb02

Funder(s)

Funder type
University/education

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

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/06/2018	11/02/2026	Yes	No