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Forced oscillation as lung function test in pulmonary rehabilitation

Submission date	Recruitment status	[_] Prospectively registered
10/07/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/07/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/08/2023	Respiratory	

Plain English summary of protocol

Background and study aims
Forced oscillation technique (FOT) is a type of lung function test, which permits to assess respiratory function. The advantage of FOT over conventional lung function techniques has already been proven for children and the elderly. In the project we plan to study the possibilities of using FOT in patients with different lung diseases admitted to the Pulmonary Rehabilitation Ward in Department of Lung Diseases and Tuberculosis in Zabrze, Medical University of Silesia, Poland.

Who can participate?
Patients with different lung diseases admitted to pulmonary rehabilitation ward

What does the study involve?
Patients will either undergo a three-week-long pulmonary rehabilitation program under physical therapist supervision or treatment as usual. The intensity of the training will be determined by the limit of heart rate obtained during a 6 minute walking test. Lung function tests and measurements of muscle strength will be performed before and after the program.

What are the possible benefits and risks of participating?
None

Where is the study run from?
Medical University of Silesia (Poland)

When is the study starting and how long is it expected to run for?
December 2017 to December 2021

Who is funding the study?
National Science Centre in Poland (Narodowe Centrum Nauki)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
2016/23/N/NZ7/0200

Study information

Scientific Title
The forced oscillation technique in patients with lung diseases subjected to pulmonary rehabilitation.

Study objectives

In the project we plan to study the possibilities of using the forced oscillation technique (FOT) in patients with different lung diseases subjected to pulmonary rehabilitation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/12/2017, Bioethics Committee of Medical University of Silesia (Poniatowskiego Street 15, Katowice, 40-055, Poland; +48 32 208 35 46; kombioet@sum.edu.pl), ref: KNW/0022 /KB1/85/I/17

Study design
Single-centre interventional non-randomized study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Lung diseases (idiopathic interstitial pneumonia, chronic obstructive pulmonary disease and patients after thoracic surgery)

Interventions
Lung function tests include: forced oscillation technique, spirometry and bodyplethysmography. All lung function tests will be evaluated before and after completing 3 weeks of pulmonary rehabilitation. All patients will perform also 6MWT and grip strength measurements of both hands. Afterwards all the results obtained before and after the rehabilitation program will be compared.

The rehabilitation program will be performed 5 days per week and will include:
- exercises on a stabilometric platform (biofeedback): once per day for 20 minutes
- breathing exercises: three times per day for 10 minutes (inspiratory muscles training, toughening and strengthening of the diaphragm)
- lumbar and cervical stabilization exercises and the equilibrium exercises: once per day for 20 minutes (PNF, strengthening of the abdominal muscles and shoulder girdle stabilization)
- general rehabilitation gymnastics once per day for 30 minutes (the elements of stretching exercises, strengthening of the arms and legs and the correction of the body posture)
- relaxation: once per day for 30 minutes (autogenic training, music therapy)
- a cycle ergometer or a treadmill: once per day for 30 minutes in the range of training heart rate

Control group will perform lung function tests (FOT, spirometry and plethysmography) in intervals of 3 weeks without pulmonary rehabilitation.

Intervention Type
Behavioural

Primary outcome(s)
1. Changes in FOT results (R5, R11, R19, X5, X11, X19, delta X, Fres, measured by oscillometer Resmon Pro Full device) - at baseline and after 3-week rehabilitation (study group)/3-week

interval (control group)
2. Changes in distance in 6MWT- at baseline and after 3-week rehabilitation (study group)

Key secondary outcome(s))
1. Changes in lung plethysmography results (Raw, RV, TLC, measured by MedGraphic Plethysmograph)- at baseline and after 3-week rehabilitation (study group)/ 3-week interval (control group)
2. Changes in spirometry results (FEV1, FVC, FEV1/FVC, measured by spirometer LungTest 1000) - at beseline and after 3-week rehabilitation (study group)
3. Changes in grip strength measured with a Meden-Inmed Baseline hydraulic hand dynamometer of left and right hand- at baseline and after 3-week rehabilitation (study group)/ 3-week interval (control group)

Completion date
30/12/2021

Eligibility

Key inclusion criteria
1. Patients with different lung diseases admitted to pulmonary rehabilitation ward
2. Informed consent provided
3. Stable period of illness without infection/exacerbation during the last 4 weeks

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Unstable angina
2. Respiratory failure
3. Anemia HgB <10g/dl
4. Bone or central nervous system metastasis
5. Low level of physical activity
6. Severe complications of operative treatment

Date of first enrolment
01/10/2018

Date of final enrolment
01/12/2021

Locations

Countries of recruitment
Poland

Study participating centre
Medical University of Silesia
Department of Lung Diseases and Tuberculosis
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Sponsor information

Organisation
Medical University of Silesia

ROR
https://ror.org/005k7hp45

Funder(s)

Funder type
Government

Funder Name
Narodowe Centrum Nauki (No 2016/23/N/NZ7/02002)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. It will be available online immediately following publication and ending 5 years following article publication.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		24/06/2022	18/08/2023	Yes	No

Results article	28/10/2022	18/08/2023	Yes	No