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Effect of pulmonary rehabilitation on clinical outcomes in patients with lung cancer

Submission date
18/07/2025

Recruitment status
No longer recruiting

Registration date
21/07/2025

Overall study status
Completed

Last Edited
21/07/2025

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study is looking at whether a supervised exercise and breathing program can help people with advanced lung cancer feel better, move more easily, and improve their quality of life while they are receiving immunotherapy. The researchers also want to see if this kind of rehabilitation can reduce inflammation in the body and help people cope better with their treatment.

Who can participate?
People aged 35 years and over who have stage IV non-small cell lung cancer and are being treated with immunotherapy may be able to join. To take part, they need to be able to walk for six minutes without using a walking aid. People with serious heart problems, certain nerve or muscle conditions, low blood counts, or other health issues may not be eligible.

What does the study involve?
Participants are randomly placed into one of two groups:
-One group takes part in a supervised rehabilitation program at the GNA “SOTIRIA” hospital in Athens. This includes 16 sessions over eight weeks, with each session lasting about an hour. The sessions include cycling, strength exercises, breathing techniques, and training to improve balance and walking.
-The other group receives usual care, which includes a single educational session about the benefits of physical activity, but no structured exercise program.
Researchers will measure changes in walking ability, muscle strength, quality of life, and blood test results at the beginning and end of the study.

What are the possible benefits and risks of participating?
There are no known risks, as all activities are supervised by trained professionals and approved by each participant’s doctor. Participants may feel better physically and emotionally, but even if they don’t benefit personally, their involvement could help improve care for future patients.

Where is the study run from?
The study is being carried out at the GNA “SOTIRIA” hospital in Athens, Greece.

When is the study starting and how long is it expected to run for?
November 2020 to October 2024

Who is funding the study?
The study is funded by the Special Account for Research Grants of the University of Thessaly through a scholarship program for doctoral candidates (Greece)

Who is the main contact?
Christina Lekka, christiana.lekka@gmail.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Effect of pulmonary rehabilitation on functional capacity, quality of life and blood inflammatory indices in stage IV lung cancer patients

Study objectives

This randomized controlled trial aims to evaluate the impact of a 16-session outpatient pulmonary rehabilitation (PR) program on multiple clinical outcomes in patients with stage IV non-small cell lung cancer (NSCLC) undergoing first-line immunotherapy, with or without chemotherapy. The primary endpoint is the enhancement of functional capacity, as measured by the distance covered during the 6-minute walk test (6MWT).

Based on the existing literature and theoretical frameworks, we hypothesize that:
1. Participation in the PR program will significantly improve functional capacity.
2. The PR intervention will lead to significant improvements in overall quality of life and will attenuate treatment-related adverse effects, particularly fatigue and dyspnea.
3. The PR program will positively influence immunotherapy efficacy, as reflected by prolongation of progression-free survival (PFS) and favorable modulation of relevant blood-based biomarkers.
4. The intervention will result in increased muscular strength and enhanced cardiorespiratory fitness.
5. The PR program will improve gait performance and related ambulatory parameters.
6. Engagement in the PR program will support improvements in fine motor dexterity.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/04/2020, Sotiria Hospital Research Ethics Committee (1st Health Region of Attica General Hospital for Chest Diseases of Athens "SOTIRIA" 152 Mesogeion Avenue, Athens, 11527, Greece; +30 -210 7757156; epi.symb@sotiria.gr), ref: 11622 / 30.4.20

Study design
Single-centre interventional randomized controlled open-label trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, University/medical school/dental school

Study type(s)
Quality of life, Efficacy

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Stage IV non-small cell lung cancer (NSCLC)

Interventions
Single-centre interventional randomized controlled open-label trial assessing the impact of a pulmonary rehabilitation program on quality of life, functional capacity, and inflammatory biomarkers in stage IV lung cancer patients receiving first-line immunotherapy.

Participants were randomized based on 6MWT performance into intervention and usual care groups, with allocation concealment maintained for those conducting the randomisation process.

Intervention Type
Behavioural

Primary outcome measure
Functional capacity measured using the 6-minute walk test (6MWT) at baseline and after completion of the 8-week pulmonary rehabilitation program.

Secondary outcome measures
1. Fine motor dexterity measured using the 9-Hole Peg Test (9HPT) at baseline and two months post-intervention.
2. Functional capacity measured using the Short Physical Performance Battery (SPPB), and isometric quadriceps force (QF) measured using the Biodex System 4 dynamometer (Biodex Medical Systems, Shirley, NY, USA) at baseline and two months post-intervention.
3. Quality of life measured using the COPD Assessment Test (CAT), the Cancer-Related Fatigue Scale (CFS), and the EQ-5D VAS scale, at baseline and two months after completion of the rehabilitation program.
4. Blood inflammatory biomarkers (NLR, PLR, LMR, SII) measured using complete blood counts at baseline and two months post-intervention .
5. Progression-free survival (PFS) assessed using radiological progression and/or significant clinical decline (e.g., new or worsening respiratory symptoms or ECOG performance status decline ≥1) at baseline and four months post-intervention.

Overall study start date
11/11/2020

Completion date
20/10/2024

Eligibility

Key inclusion criteria
1. >35 years
2. Receiving immunotherapy as primary treatment
3. Had not undergone thoracic surgery and
4. Were able to walk 6 minutes without walking aids

Participant type(s)
Healthy volunteer, Patient

Age group
Adult

Lower age limit
35 Years

Upper age limit
85 Years

Sex
Both

Target number of participants
72

Total final enrolment
72

Key exclusion criteria
1. History of cognitive or neuromuscular disorders
2. Musculoskeletal impairments affecting walking ability and inability to read and understand Greek language
3. Patients with ECOG performance status ≥2
4. Unstable cardiac disease
5. Dyspnoea classified as NYHA class II-IV
6. Recent cerebrovascular event
7. Thrombocytopenia (platelet count<50,000/μ L)
8. Low hemoglobin levels (<10.0g/dl)
9. High risk of pathological fracture as determined by the Mirel's scoring system and Brief Pain Inventory (BPI) for bone pain

Date of first enrolment
06/12/2022

Date of final enrolment
10/10/2024

Locations

Countries of recruitment
Greece

Study participating centre
Rehabilitation Unit, 1st University Department of Respiratory Medicine, "Sotiria" Hospital, Medical School, National and Kapodistrian University of Athens
Mesogeion 152
Athens
Greece
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Study participating centre
Oncology Unit, 3rd Department of Medicine, "Sotiria" Hospital for Diseases of the Chest, National and Kapodistrian University of Athens
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Greece
11527

Sponsor information

Organisation
University of Thessaly Innovation, Technology Transfer Unit and Entrepreneurship Center "One Planet Thessaly"

Sponsor details
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Sponsor type
Government

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Funder(s)

Funder type
University/education

Funder Name
University of Thessaly

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Greece

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
30/09/2025

Individual participant data (IPD) sharing plan
Individual participant data will be shared upon reasonable request form christiana.lekka@gmail.com. Data will be anonymized and made available via institutional repository after publication.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			21/07/2025	No	No