Recovery of Physical and Psychological health, and Health-Related Quality of Life (HRQoL) in lung cancer patients six months following lung resection.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON37418

Source
ToetsingOnline

Brief title
Recovery after Lung Resection

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified
- Respiratory tract neoplasms
- Respiratory tract therapeutic procedures

Synonym
lung cancer, lung resection

Research involving
Human

Sponsors and support

Primary sponsor: Revalidatiecentrum Het Roessingh
Source(s) of monetary or material Support: Alpe d'Huzes/KWF

Intervention

Keyword: Health status, Lung cancer, Lung resection, Quality of Life

Outcome measures

Primary outcome

The primary outcome measures of this study are:

- Exercise capacity (VO2peak with maximal cycle test (CPET))

- Distress (HADS)

- Physical Functioning subscale of the EORTC C30

Secondary outcome

Lung functioning (total spirometry)

Quality of Life (EORTC C30 and LC13)

Physical functioning (6MWT and 30 seconds Chair Stand Test)

Pain (BPI)

Fatigue (MFI)

Self-efficacy (SES)

Coping strategies (MAC)

Daily physical activity patterns(accelerometer and IPAQ)

Disabilities and Participation (Last-meter)

Healthcare use

Healthcare need

Study description

Background summary

Although lung resection is the preferred treatment for early-stage lung cancer, it causes a considerable decay of physical health, Health-Related Quality of Life (HRQoL), and psychological functioning. Prospective studies in lung cancer patients treated with lung resection, mainly focused on the recovery of physical health (such as lung function and exercise capacity), and HRQoL. However, these outcome measures have been measured largely independent from each other. Furthermore, recovery may further be complicated by psychological symptoms. So far, little evidence from prospective studies is available to clarify the prevalence and development of psychological distress following lung resection. Lastly, it is unknown whether lung cancer patients treated with lung resection feel the need for post-surgery rehabilitation. Hence, there is a need for studies with a more holistic approach in which the recovery of physical and psychological health status, and HRQoL after lung resection is explored simultaneously, and tested multiple times following surgery. Also, we believe that it is necessary to assess perceived *healthcare need* in this specific population. These insights can be used for the future optimization of rehabilitation programs for lung cancer patients treated with lung resection.

Study objective

The main aim of this study is to explore the recovery of physical and psychological health status, and HRQoL simultaneously in lung cancer patients that have undergone lung resection in the Netherlands. Next to that, we hope to identify the perceived need for rehabilitation.

Study design

A prospective cohort study will be performed to answer the research questions.

Study burden and risks

The risks associated with participation in the study are considered small. Patients will receive regular care complemented with several questionnaires, interviews, activity monitoring and easy to perform physical performance tests. The activity monitor will cause no restriction on daily activity performance. The physical performance test, such as the 6MWT and the 30-CST, are executed at their own pace and heart rate is monitored continuously during the 6MWT. Although the cardiopulmonary exercise test (CPET) pushes the patients to their maximal cardiopulmonary level, only patients that are approved by their lung physician or lung surgeon will be tested. Furthermore, this test will be executed by trained personal, heart functioning will be monitored during

testing, and testing is stopped by signs of symptoms.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

a) Age 18 * 80 years;
b) Histologically confirmed or suspected lung cancer;
c) Scheduled or on waiting list for lung resection with curative intention.

Exclusion criteria

a) Not able to perform basic skills like sitting, lying down or walking;

b) Cognitive disorders not cancer-related;
c) Severe emotional instability which will hamper study participation;
d) Uncontrolled cardiovascular and/or neurological disease;
e) Not able to understand Dutch or English (written and/or verbal);
f) Palliative treatment.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-08-2012
Enrollment:	51
Type:	Actual

Ethics review

Approved WMO

Date:	30-05-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL38848.031.11