Pulmonary rehabilitation after minimal invasive surgery in lung cancer.

Published: 08-11-2018
Last updated: 10-04-2024

To evaluate the effect of integrated multidisciplinary rehabilitation on quality of life (QOL) in the 12 months postoperative phase in patients with lung cancer undergoing minimal invasive surgery.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON46834

Source
ToetsingOnline

Brief title
PROMISE

Condition

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

Synonym
bronchial carcinoma, lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Isala Academie

Intervention

Keyword: Lung cancer, RATS, Rehabilitation, VATS

Outcome measures

Primary outcome

Effects on quality of life will be our main endpoint, this will be tested with

the following questionnaires: short form health survey (SF-36),

Secondary outcome

- Pulmonary health related quality of life (SGRQ score)

- Acute / chronic score (VAS)

- Impairment (changes in pulmonary function)

- Performance score (WHO)

- Disability / exercise capacity (6MWD and iPAQ)

Study description

Background summary

A lobectomy or pneumonectomy is an operation with curative intention in a selected population with lung cancer. After the operation the disease is considered as cured but recovery of the patient takes more time. The physical, mental and social problems associated with the disease and treatment are just at their beginning. Physical complaints as pain and loss of exercise tolerance are a limiting factor (2-4). Disability to participate in the daily routine, social life and work will lead to impairment in the social context. Mental and psychological effects due to the confrontation with health failure may increase disease burden.

All these different domains are related to the patients* quality of life (QOL). Previous reports showed a decrease in QOL during the first 6 months after surgery, with recovery afterwards (5,6). The multifactorial postoperative problems ask for an integral approach with patient centred care from different perspectives: multidisciplinary rehabilitation.
In 2013 we conducted a study in our hospital to investigate post-operative

rehabilitation in lung cancer. In a randomised controlled trial patients undergoing thoracotomy received additional care and treatment of physical therapists, the pain clinic and social workers to investigate the effect on QOL(1). The main finding was an increased exercise tolerance without an increase in QOL. The intervention group experienced more pain, which had a negative effect on QOL. The increase in pain was explained due to the extensive and mutilating operating technique of thoracotomy. As a result, we did not implement multidisciplinary rehabilitation as standard care.
Since 2013 the thoracotomy has been replaced by minimal invasive surgery (MIS). Video-assisted thoracoscopic (VATS) and robot-assisted thoracoscopic surgery are the new standard operating techniques. A recently randomised control trial showed improvement in both post-operative pain levels and QOL after VATS compared to thoracotomy (7).
These findings associated with the minimal invasive surgery opens new opportunities for multidisciplinary rehabilitation.

Study objective

To evaluate the effect of integrated multidisciplinary rehabilitation on quality of life (QOL) in the 12 months postoperative phase in patients with lung cancer undergoing minimal invasive surgery.

Study design

The study conducted will be a prospective randomised controlled trial, between multidisciplinary rehabilitation and standard care.

Intervention

The intervention group is given an integrated multidisciplinary rehabilitation program consisting of extensive physical training program for 3 months, visits to the pain clinic, visits to the social worker and, if indicated to the psychologist.

Study burden and risks

Our intervention group will follow a prespecified physical training programme for 3 months. In these three months our patients will be invited to train two times a week in the hospital under supervision of oncologic qualified physical therapists. The intervention group will have at least one scheduled visit to the pain clinic. If necessary further visits to the pain clinic will be scheduled. All patients will visit the social worker and a psychologist if indicated. Both intervention and standard care groups will receive questionnaires at prespecified times. There will be no additional number of blood samples. Our trial nurse will guard the physiological and physical burden

associated with our study by frequently contacting the patients.

Contacts

Public
Isala Klinieken

dr. van Heesweg 2
Zwolle 8025 AB
NL
Scientific
Isala Klinieken

dr. van Heesweg 2
Zwolle 8025 AB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

lungcancer
minimal invasive pulmonary surgery
age between 18 - 80 years
ECOG 0 - 2 post-operative

Exclusion criteria

1. Patients with chronic pain
2. Previous pulmonary surgery
3. Comorbidity limiting rehabilitation

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-05-2019
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	08-11-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	21-01-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	29-01-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL63724.075.18