Pulmonary rehabilitation after minimal invasive surgery in lung cancer.

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26608

Source
Nationaal Trial Register

Brief title
PROMISE

Health condition

lung cancer, post operative pain, VATS, RATS, longkanker

Sponsors and support

Primary sponsor: Isala Zwolle
Source(s) of monetary or material Support: Isala Innovatie en Wetenschapsfonds

Intervention

Outcome measures

Primary outcome

To evaluate the effects of an integrated multidisciplinary rehabilitation program on general quality of life (short form 36, SF-36, subdomain general health) in the 12 months postoperative period in patients undergoing elective minimal invasive surgery in lung cancer.

Secondary outcome

To evaluate the effects of the program on health-related quality of life (SGRQ), post-operative pain (VAS), performance score (WHO-PS), exercise tolerance (6 minute walking distance, 6MWD) and physical activity (international physical activity questionnaire, iPAQ).

Study description

Background summary

Rationale: Morbidity in the post-operative phase of pulmonary surgery is characterised by impairment due to pain, dyspnoea and loss of exercise tolerance. We demonstrated previously that rehabilitation after thoracotomy is limited due to pain (1). Since minimal invasive surgery is the new standard in lung cancer, resulting in a reduction of postoperative pain, we believe there are new possibilities for post-operative integrated multidisciplinary rehabilitation in lung cancer.

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.

Study population: All patients between 18 and 80 with lung cancer undergoing minimal invasive surgery (video-assisted or robot assisted thoracoscopic surgery).

Intervention (if applicable): The intervention group will have an integrated multidisciplinary rehabilitation program consisting of an extensive physical training program for 3 months, visits to the pain clinic, visits to the social worker and, if indicated to the psychologist.

Main study parameters/endpoints: Effects on quality of life will be our main endpoint. T this will be tested with the following questionnaires: short form health survey (SF-36), St. George Respiratory questionnaire (SGRQ) and the World Health Organization Performance Score (WHO-PS). Furthermore, pain scores will be monitored with the visual analogue scale (VAS).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Our intervention group will follow a 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. The physiological and physical burden associated with our study will be guarded by a trial nurse who will frequently contact the patients.

Study objective

Morbidity in the post-operative phase of pulmonary surgery is characterised by impairment due to pain, dyspnoea and loss of exercise tolerance. We demonstrated previously that rehabilitation after thoracotomy is limited due to pain. Since minimal invasive surgery is the new standard in lung cancer, resulting in a reduction of postoperative pain, we believe there are new possibilities for post-operative integrated multidisciplinary rehabilitation in lung cancer.

Our main goal is to evaluate the effects of an integrated multidisciplinary rehabilitation program on general quality of life (short form 36, SF-36, subdomain general health) in the 12 months postoperative period in patients undergoing elective minimal invasive surgery in lung cancer.

Study design

After inclusion patients will follow a prespecified rehabilitation course, tests and questionaires will be conducted during one year follow up after surgery.

Intervention

multidisciplinary rehabilitation

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

Patients undergoing minimal invasive surgery for lung cancer, ages between 18 and 80 years.

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

1. Patients undergoing elective, minimal invasive surgery with intention to cure.

2. Age between 18 and 80 years.

3. ECOG 0 – 2 post-surgery.

Exclusion criteria

1. Patients with chronic pain

2. Previous pulmonary surgery

3. Comorbidity limiting rehabilitation

a. Rheumatoid arthritis

b. Severe ischaemic heart disease or myocardial failure; EF ≤ 35 %.

c. Muscle disease

d. Fibromyalgia

e. Neurologic disorders (Parkinson disease, CVA and lesions of the spinal cord)

f. Psychiatric disorders

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-01-2019
Enrollment:	100
Type:	Unknown

Ethics review

Positive opinion

Date:	10-12-2018
Application type:	First submission

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
NTR-new	NL6386

Register	ID
NTR-old	NTR7658
Other	: ABR 63724

Study results