Pulmonary rehabilitation after minimal invasive surgery in lung cancer.

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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…

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26608

Bron
Nationaal Trial Register

Verkorte titel
PROMISE

Aandoening

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

Ondersteuning

Primaire sponsor: Isala Zwolle
Overige ondersteuning: Isala Innovatie en Wetenschapsfonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

multidisciplinary rehabilitation

Contactpersonen

Publiek

Wetenschappelijk

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-01-2019
Aantal proefpersonen:	100
Type:	Onbekend

Ethische beoordeling

Positief advies

Datum:	10-12-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6386
NTR-old	NTR7658
Ander register	: ABR 63724

Resultaten