

# Daily physical activity of lung cancer surgical patients: A pilot study

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To examine the predictive value of daily physical activity (steps/day) (DPA) of lung cancer surgical patients, measured by a pedometer, on postoperative morbidity. To examine the relationship between the daily physical activity (pedometer-assessed...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Respiratory tract therapeutic procedures
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON30862

### Source

ToetsingOnline

### Brief title

DPA of lung cancer surgical patients

### Condition

- Respiratory tract therapeutic procedures

### Synonym

lung cancer, Non-small cell lung cancer

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Lung cancer, Physical activity, Postoperative complications, Resection

## Outcome measures

### Primary outcome

This study will use following parameters: daily physical activity (steps/day) (DPA) and postoperative complications/morbidity.

### Secondary outcome

Age (years)

Sexe

Pulmonary function in FEV1

Size of operation (lobectomy, bi-lobectomy or pneumectomy)

Type of lung malignancy (squamous cell carcinoma, adenocarcinoma, large cell carcinoma)

Co-morbidity (Charlson scale, Charlson et al., 1987)

Performance score ECOG (Oken et al, 1982, Karnofsky)

Physical capacity in METs (from SQUASH test)

Physical capacity in METs (from questionnaire anesthetist)

## Study description

### Background summary

Operations in the thorax or upper abdomen, like lung resection surgery in patients with localized non-small cell lung cancer (NSCLC) (stages I, II and IIIA), are high-risk surgeries (Wiener-Kronish et al. 2005).

During the last two decades, better preoperative cardiopulmonary evaluation and postoperative management have led to a decline in complications and postoperative mortality of lung resection surgery patients (Perrot et al.,

1999). However, as a result of the increased proportion of older patients ( $\geq 70$  years), the incidence of associated co-morbidity has increased during this period (Morandi et al., 1996). Consequently this change in patient characteristics results in an increased importance of the preoperative risk estimation.

## **Study objective**

To examine the predictive value of daily physical activity (steps/day) (DPA) of lung cancer surgical patients, measured by a pedometer, on postoperative morbidity.

To examine the relationship between the daily physical activity (pedometer-assessed ambulatory activity) and the metabolic equivalent (MET) levels of lung cancer surgical patients, obtained by questionnaires of the anesthetist.

## **Study design**

Psychometric study to the predictive validity of a risk screening instrument.

A correlation analysis and ROC curve analysis of performance based daily physical activity monitoring (steps/day) and regular preoperative anaesthetic screening (MET score) related to postoperative complications will be performed.

A survival analysis (Cox regression) will be used to examine the predictive validity of DPAM (Daily Physical Activity Monitoring) and RPAS (Regular Preoperative Anesthetic Screening by using METs scores) .

A logistic regression analysis of addition of the factor daily physical activity (DPA) to the preoperative anaesthetic screening and the effect of these factors plus DPA on the postoperative morbidity was also carried out.

The study will take eighteen months. The patient will participate two weeks before surgery and 14 days after surgery his postoperative complication status will be seen.

## **Study burden and risks**

The extent of the burden is minimal. The participants fill in a short questionnaire. This will take 15 minutes. In addition, the patients will wear a pedometer for maximal 14 days.

## **Contacts**

### **Public**

Universitair Medisch Centrum Groningen

Hanzeplein 1

9700 BR Groningen  
Nederland  
**Scientific**  
Universitair Medisch Centrum Groningen

Hanzeplein 1  
9700 BR Groningen  
Nederland

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Willingness to comply with the research protocol

Non-Small Cell Lung Cancer (NSCLC) patient in the UMCG receiving lung resection surgery within  $\pm 7$  days

Ambulatory (not bedridden)

Diagnosis of TNM stages I and II

### Exclusion criteria

Use of wheelchair

Significant co-morbidity interfering with (daily) physical activity

## Study design

## Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

## Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 12-11-2007

Enrollment: 175

Type: Anticipated

## Ethics review

Approved WMO

Application type: First submission

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**

CCMO

**ID**

NL18464.042.07