Obesity in lung transplant recipients: the role of daily physical activity, food intake, resting energy expenditure

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The aim o this study is to examine the cause(s) of large increases in weight after lung transplantation; the effect of daily physical activity, daily food intake and resting energy expenditure will be investigated in COPD and lung fibrosis lung...

Ethical review	Approved WMO
Status	Pending
Health condition type	Appetite and general nutritional disorders
Study type	Observational non invasive

Summary

ID

NL-OMON33805

Source ToetsingOnline

Brief title Obesity in lung transplant recipients

Condition

• Appetite and general nutritional disorders

Synonym lung transplantation, obesity

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: daily physical activity, lung transplant recipients, obesity, resting metabolic rate

Outcome measures

Primary outcome

Body composition: Body mass index and fat-free mass

Weight and fat-free mass will be measured by a Bioelectrical Impedance Analysis (bodystat 1500). The high correlation coefficient (r = 0.974), small bias and standard estimation of error of a Bioelectrical Impedance Analysis, makes it able to predict fat-free mass in pre- and post transplant patients.

Daily physical activity, performance based

Daily physical activity was assessed on a performance basis by the Digiwalker SW-200 (Yamax; Tokyo, Japan). This pedometer has proved to accurately detect steps taken, as an indication of volume of daily physical activity. It has also shown evidence of reliability and convergent and discriminative validity. In this study patients are instructed to wear the pedometer during ten days (until going to bed), and to record the number of steps per day. The number of minutes that they are swimming, doing fitness or cycling will be reported in a diary and will be converted into steps. Steps/day including the converted steps will be expressed as step equivalents. The last seven out of ten daily-records will be used for further processing.

Daily physical activity, questionnaire based

Daily physical activity was assessed in self-reported fashion with the Short 2 - Obesity in lung transplant recipients: the role of daily physical activity, food ... 4-05-2025 QUestionnaire to ASsess Health-enhancing physical activity (SQUASH). This questionnaire is designed to give an indication of the habitual activity level, and has shown to be a fairly reliable and reasonably valid questionnaire (r = 0.36-0.74). It was expressed in MET/min (MET: ratio of exercise metabolic rate to resting metabolic rate) and total minutes a week.

Food intake

Food intake will be estimated by a dietitian using an extensive food anamnesis.

Resting Metabolic Rate

Resting metabolic rate (RMR) will be measured using the ventilated-hood technique. Criteria for a valid RMR are: a minimum of 15 minutes of steady state, the participants should not have eaten food 4 hours before the measurement, testing will be in the morning. RMR will be measured for 15-20 minutes.

Secondary outcome

Fatigue

Fatigue based on daily activities in household, body care and social activities will be measured with the Dutch Exertion Fatigue Scale (DEFS). The DEFS contains nine questions, which have to answered on a five-point score ranging from 0 (no) to 4 (yes). A low score on the DEFS represents a low score on fatigue of daily activities (reliability: Cronbach*s alpha 0.91).

Lower body strength

Lower body strength is assessed using the sit-to-stand test. Lower body strength plays an important role in every-day-activities. This test involves counting the number of times, within 30 seconds, that the patient can come to a full stand from a seated position without using his arms. The 30-second sit-to-stand test has been shown to be reliable (test-retest correlation r =0.80) and has been validated against the gold standard measure for lower-body strength, the leg-press test. According to Rikli and Jones, intraclass reliability is r = 0.89 (test-retest) and criterion validity related to leg press is r = 0.77 (test-retest).

Study description

Background summary

Lung transplantation is a one of the treatment options in patients with an end-stage lung disease. Although some weight gain after lung transplantation is desirable, excessive gain in body fat should be avoided. A part of the lung transplant recipients develops an overweight, while another part doesn't. It is important to examine the mechanism of the excessive weight gain after lung transplantation. The outcomes of this study can help prevent or reduce overweight/obesitas in lung transplant recipients.

Study objective

The aim o this study is to examine the cause(s) of large increases in weight after lung transplantation; the effect of daily physical activity, daily food intake and resting energy expenditure will be investigated in COPD and lung fibrosis lung transplant patients.

Study design

The study is a cross-sectional, observational study. This study is combined with a visit to the outpatient clinic of the UMCG. Each measurements will take approximately 120 minutes.

Study burden and risks

The tests and interview with the dieticien will take 120 minutes. The participants also have to wear a pedometer for 10 days.

Contacts

Public Universitair Medisch Centrum Groningen

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Hanzeplein 1 9700 RB Groningen Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

All

- Age>18 years
- Lung transplantation >1year ago
- Underlying disease state COPD or lung fibrosis
- Able to undergo the study related assessments

- Written informed consent

Overweight/obese

- Weight gain >10% since lung transplantation
- Actual BMI>25 kg/m2
- Normal weight
- BMI 20-25 kg/m2
- Weight gain <2kg in last 6 months

Exclusion criteria

- not able to walk independently
- symptoms of rejection of the lung
- recipients who just started a diet or changed there eating habits
- Other underlying extra-pulmonary disease state that may interfere with the study outcome

Study design

Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Basic science	

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-01-2009
Enrollment:	44
Туре:	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** NL25568.042.08