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PROLUCA

Postoperative Rehabilitation in Operation for LUng CAncer (PROLUCA) – Rationale and Design

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PURPOSE

The purpose of the PROLUCA study is to investigate the efficacy of early postoperative rehabilitation in a non-hospital setting in patients with operable lung cancer, with special focus on exercise training.

DESIGN/METHODS

One hundred and seventy (n=170) participants (85 patients/ study arm) with Non-Small Cell Lung Cancer (NSCLC),stage I-IIIa, referred for surgery, will be recruited and randomized to one of the following two groups:
(1) Early postoperative rehabilitation initiated as early as two weeks after surgery
(2) Postoperative rehabilitation initiated 14 weeks after surgery
The inclusion criteria are: At least 18 years old, performance status 0-2 (WHO), living in the city of Copenhagen or surrounding municipalities, approval by primary surgeon and ability to read and understand Danish. The exclusion criteria are: Presence of metastatic disease or severe cardiac disease.

POWER

In previous studies the response within each intervention group was normally distributed with standard deviation 4 $mLO_2 \cdot kg^{-1} \cdot min^{-1}$. If the true difference in the experimental and control mean values is 2 $mLO_2 \cdot kg^{-1} \cdot min^{-1}$, we will need to include 85 participants in both groups to be able to reject the null hypothesis, that the population means of the experimental and control groups are equal with probability (power) 90%. The Type I error probability associated with the test of this null hypothesis is 5%.

INTERVENTION

The intervention consists of a supervised group exercise program comprising resistance and cardiorespiratory exercise two hours weekly for 12 weeks combined with individual counseling. Cardiorespiratory exercise is at an intensity ~ 60-90% of individually determined heart rate max and resistance exercise is at ~60-80% of 1 RM. All interventions will be individually tailored to each participant and following the principles of aerobic or resistance exercise prescription guidelines for adults as recommended by the American College of Sports Medicine (ACSM).

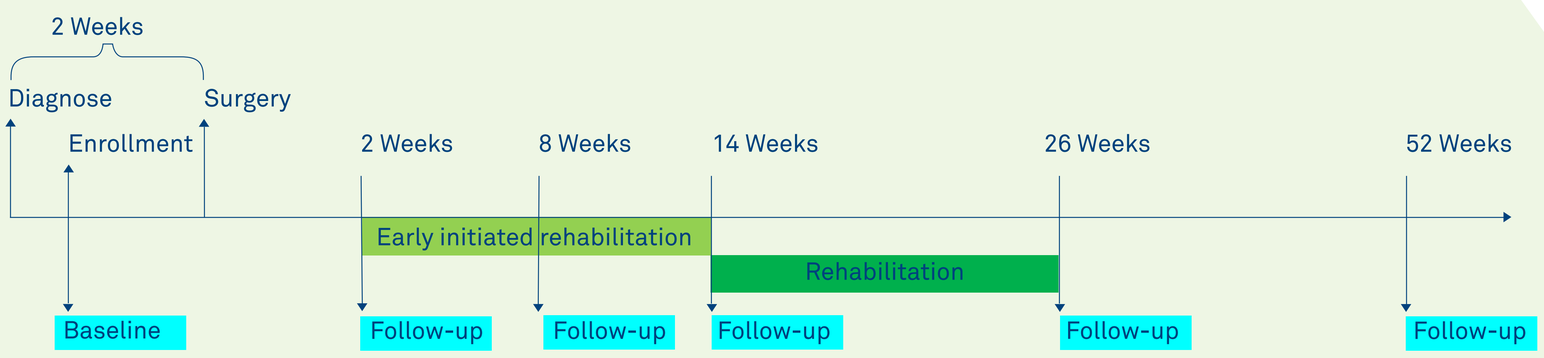


Figure 1. PROLUCA: STUDY TIMELINE

The primary study endpoint is:
- Maximal oxygen uptake measured by a VO_2peak test (direct measurement)

Secondary endpoints include:
- Six minutes walk distance (6MWD)
- One-repetition-maximum (1RM)
- Patient-reported outcomes (PROs) on health related quality of life, fatigue, depression, lifestyle etc.
- Postoperative complications (registered prospectively up to 30 days after surgery)
- Hospitalization time
- Sick leave and work status
- Survival

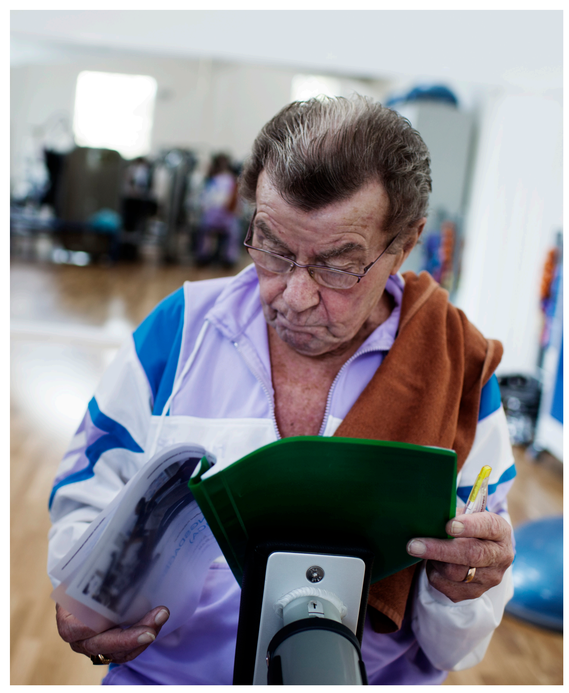
Endpoints will be assessed:
- Pre surgery at baseline (all endpoints)
- Postoperatively at:
  - Two weeks (6MWD, FEV_1, FEV_1%, PROs)
  - Eight weeks (6MWD, FEV_1, FEV_1%, PROs)
  - Fourteen weeks (all endpoints)
  - Half a year (all endpoints)
  - One year (all endpoints)

RESULTS

The results of PROLUCA will identify the optimal timing of postoperative rehabilitation in NSCLC patients with focus on increasing physical capacity and health related quality of life and reducing the side effects from the treatment of the cancer disease.

DISCUSSION

To our knowledge this is the first study to report data on postoperative rehabilitation initiated as early as two weeks after surgery in NSCLC patients. This group of patients is in exceedingly needs of rehabilitation to decrease comorbidity, relapse of the cancer disease and even to prolong life. PROLUCA is unique, compared to other studies, where the selection of patients is distinct, and therefore PROLUCA is of potential importance to daily clinical practice.



Photos: Anne Mie Dreves

Acknowledgements
The study is supported by grants from The Center for Integrated Rehabilitation of Cancer patients (CIRE), a center established and supported by The Danish Cancer Society and The Novo Nordisk Foundation and the study is supported by the Copenhagen University Hospital, the Faculty of Health Sciences, University of Copenhagen, and is secured by funding from The Municipality of Copenhagen.

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