Photos: Adam Mørk

www.kraeftcenter-kbh.dk

PROLUCA

PROLUCA (Perioperative Rehabilitation in Operation for LUng CAncer) – Rationale, design and result of a feasibility study

Karen Trier, Maja S. Sommer, Jette Vibe-Petersen, Malene Missel, Merete Christensen, Carsten Hendriksen, Seppo W. Langer, Klaus Richter Larsen, Paul Clementsen, Henning Langberg and Jesper Holst Pedersen

PROLUCA

PURPOSE
The purpose is, in a non-hospital setting, to investigate the efficacy of preoperative and early postoperative rehabilitation with focus on exercise training in patients undergoing surgery for lung cancer.

METHODS
Using a 2 x 2 factorial design with continuous effect endpoint (VO2peak), 380 subjects (95 patients/study arm) with histological evidence of non-small cell lung cancer (NSCLC) at disease stage I-IIIa, referred for surgical resection at Department of Cardiothoracic surgery RT, Rigshospitalet, will be randomly assigned to one of four groups (three intervention groups and one control group). (Figure 1)

The preoperative rehabilitation program consists of an individually designed, 30 minutes daily, home exercise program.

The postoperative rehabilitation program consists of a supervised group exercise program comprising resistance and cardiovascular training two hours weekly for 12 weeks (exercise intensity at 60-90% of VO2peak) combined with individual counseling.

The primary study endpoint is VO2peak (ml oxygen/kilo/minute)(direct measurement). Secondary endpoints include: Perioperative complications (registered prospectively up to 30 days after surgery), 6 MWT (distance), 1 RM (kilo), patient-reported outcomes (e.g., quality of life, fatigue, depression, lifestyle etc.), hospitalization time, sick leave and work status, and survival.

All endpoints will be assessed at baseline, the day before surgery and postoperatively, at week 26 and 52.

RESULTS
The results of PROLUCA will identify the optimal perioperative rehabilitation for NSCLC patients with focus on reducing the side effects from the treatment by improving activity of daily living and quality of life through exercise training initiated immediately after diagnosis and surgery.

CONCLUSION
This is the first study to evaluate preoperative training on a larger scale and initiate exercise as early as 2 weeks postoperatively, and the study will provide insights on the dose and progression of early exercise in rehabilitation of lung cancer patients.

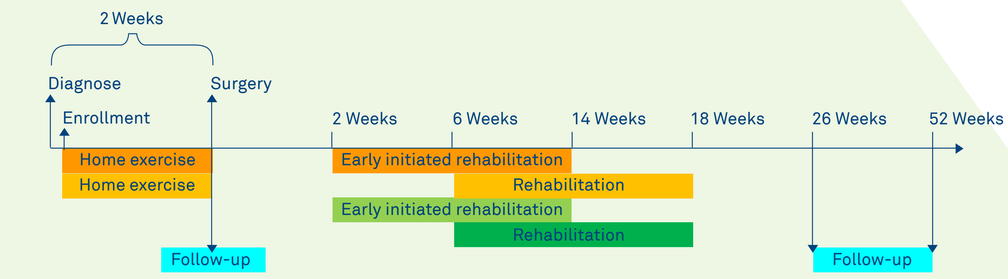

Figure 1. PROLUCA: STUDY TIMELINE
(three intervention groups and one control group)

PROLUCA FEASIBILITY STUDY

BACKGROUND
The purpose of the study was to investigate the safety and feasibility of the most experimental intervention planned for participants in PROLUCA.

METHODS
Fifteen subjects with histological evidence of NSCLC, at disease stage I-IIIa, were included in a preoperative rehabilitation program using the above-mentioned (PROLUCA) pre- and post-operative rehabilitation program initiated two weeks after surgery.

RESULTS
Recruitment took place between January 2012 and March 2012. Twelve patients carried out the preoperative training and were tested again prior to surgery. Seven of these patients completed the postoperative rehabilitation program, and no adverse events were observed during the intervention.

Eight patients were not able to participate in the early postoperative exercise program: 3 of these died within 2-4 months after surgery, 2 were lost to follow up, 3 did not want to start exercise as early as 2 weeks after surgery. The preoperative exercise resulted in an average 4 % improvement in 6 MWT (distance). The postoperative rehabilitation initiated 2 weeks after surgery was only applicable for the best half of the patients, and the inability to participate in exercise training early after surgery may be a negative prognastic factor.

CONCLUSIONS
The feasibility study indicated that the PROLUCA perioperative rehabilitation program for patients with NSCLC is safe and feasible.

Photos: Anne Mie Dreves

The PROLUCA trial is carried out in collaboration between Copenhagen Centre for Cancer and Health, Rigshospitalet, Bispebjerg Hospital, Gentofte Hospital and University of Copenhagen. The Copenhagen Centre for Cancer and Health offers free rehabilitation programs to all citizens of Copenhagen who have or have had cancer. PROLUCA is a trial related to CIRE, a center established and supported by The Danish Cancer Society and the Novo Nordisk Foundation.

CENTER FOR KRÆFT & SUNDHED KØBENHAVN

REGION H Rigshospitalet