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supportive care

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ACCERT: AUCKLAND'S CANCER CACHEXIA EVALUATING RESISTANCE TRAINING STUDY

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Background: Cancer Cachexia (CC) is a common problem seen in many advanced malignancies including Non- Small-Cell Lung Cancer (NSCLC). In CC there is a significant loss of adipose tissue and skeletal muscle mass. Muscle wasting is the main cause of impaired function, leading to respiratory complications and fatigue. The optimal treatment for CC is the complete removal of the tumour; unfortunately with advanced NSCLC this is unachievable. The next best options are to increase nutritional intake to counteract weight loss, address the anorexia, inflammation, and metabolic alterations i.e. loss of body fat and the skeletal muscle wasting. This requires the need to utilise a multi-targeted approach to decrease the inflammation and to stimulate the skeletal anabolic pathways with the use of progressive resistance training (PRT). PRT has shown acceptability and benefits in other cancer populations. This study aims to identify a novel multi-targeted treatment regimen that will alleviate and/or stabilise CC weight loss.

Methods: This is a randomised, open-label study to investigate whether 2 sessions each week of PRT followed by essential amino acids (EAA's) high in leucine, when administered in addition to Eicosapentaenoic Acid (EPA) and a Cox-2 inhibitor is acceptable to NSCLC cachectic patients for a period of 20 weeks (primary endpoint). Secondary endpoints include Lean Body Mass, MRI thigh skeletal muscle values, QoL and Fatigue questionnaires, serum pro-inflammatory cytokine profiles, and hand and leg strength. Safety data will also be collected. Outcome measures to power a future study will be determined from the trend in difference between the two groups. 21 patients are planned to be randomised in a 1:2 ratio Arm A EPA and Cox-2 inhibitor vs. Arm B EPA, Cox-2 inhibitor, PRT followed by EAA's. All patients are offered to continue with the study medications and/or PRT sessions on compassionate use. Main inclusion criteria include: histological proven NSCLC patients who have at least 5% weight loss and fulfil the following cachectic definition (Evans Clin Nut 2008 27). A guest patient was enrolled in May 2012, followed by study participants in June 2012.

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