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**A pilot randomised controlled trial of megestrol acetate and prednisolone for anorexia and weight loss in patients with lung cancer or mesothelioma**

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**Introduction:** Corticosteroids and synthetic progestogens are widely used to treat anorexia in cancer patients, though their overall effect on quality of life is not established. In this pilot study we assess the feasibility of quality of life (QoL) as the primary endpoint of a randomised trial comparing prednisolone, megestrol acetate and the combination.

**Methods:** We performed a prospective, randomised, open, multicentre trial comparing prednisolone 30mgs daily for 2 weeks, megestrol 160 mgs bd for 8 weeks and a combined arm. The trial was performed in specialist lung cancer clinics in one teaching hospital and three district general hospitals. The EORTC QLQ-C30 and LC-13 Lung module QoL was assessed at baseline, 2, and 8 weeks. Dietary intake was assessed by using three day diet diaries. Eligible patients had a diagnosis of lung cancer or mesothelioma, a Karnofsky score of  $\geq 70$  and significant anorexia or unintentional weight loss of  $>5\%$ .

**Results:** The study was closed with 39 patients recruited in 2 years, only 50% completing the three out-patient visits. 27 patients were male and all had a diagnosis of lung cancer. The median age was 72 (range 51-83), and Karnofsky score was 80 (range 70-90). In patients completing the 3 visits, compliance was good with 88% of required data collected and recorded. Data was collected from QoL and dietary diary card which was valid and of good quality. Statistical comparison was inappropriate because of small number of patients recruited.

**Conclusion:** This pilot study indicates that QoL and diary card data can be used as a valid endpoint for studies in this area. For future trials to succeed recruitment and patient drop out needs to be addressed. Future studies will need to recruit from palliative and primary care clinics and incorporate home visits or telephone follow up to maximise the data collection.