Title: The results of the prevalence screen in Lung SEARCH: A UK based screening trial for lung cancer based on sputum cytology and cytometry, by the Lung SEARCH screening group

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Body: Lung SEARCH is a screening trial in 9 UK centres of 1658 subjects with a >20 pack year smoking history, mild or moderate chronic obstructive pulmonary disease (COPD). Randomisation was to a control group who had no active intervention, but an exit chest X-ray (CXR) at the end of 5 years; or a surveillance group who provide sputum samples annually for 5 years, for cytological and cytometrical analysis, and if normal for the duration of the study, an exit CXR. Samples showing abnormalities would undergo annual low-dose computed tomography (CT) and autofluorescent fibreoptic bronchoscopy (AFB) for the remaining years of the five. Our aim is to identify more early stage cancers in the surveillance arm (>50%) than the control (<10%) and literature on COPD suggested we would need 37 cancers in each study group. We entered 785 subjects into the surveillance, and 783 in the control arms. The two groups were well matched with 52% of men in both groups, 56% and 44% in each group were current or ex-smokers, and their mean ages were 63 years. 75% in each group had moderate COPD and 25% were mild. Results: Of the 785 subjects in the surveillance arm, 92% provided a sputum sample. Of these only 132 of 742 were inadequate for analysis. 532 (73%) were normal, 128 (17%) were abnormal: 16 were high grade and 112 low grade. All 128 are being followed by CT and AFB. Conclusions: Sputm cytology/cytometry performed within a high risk population gave a higher than expected yield of abnormal samples. The study may prove a promising and cost effective method to identify those at very high risk of developing early lung cancer.