

## OP05.1

### **An RCT of a biomarker blood test in lung cancer using the EarlyCDT-Lung test in Scotland: provisional data from the 1st 10 000 patients**

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**Background & Aim:** Since the majority of lung cancer cases are detected at a late stage the prognosis remains poor at present. The National Lung Screening Trial (NLST) reported 20% reductions in lung cancer mortality in 2011, however as a primary screening modality CT is expensive and may lead to significant morbidity in individuals whose tests are false positives. The EarlyCDT-lung test detects autoantibodies to proteins in the earliest stages of the disease with a specificity of 93%.

**Method:** We are conducting an RCT in areas of Scotland within the most deprived quintile of the population whose mortality from lung cancer is high by international standards. Adults aged 50 to 75 who are at 1.2% risk over the next 2 years are eligible to participate. They should also be healthy enough to undergo curative interventions. We will undertake a comparison of the EarlyCDT-lung test and follow-up imaging at six monthly intervals for 2 years with standard clinical practice. The primary outcome is the difference, after 24 months, between the rates of patients with stage 3, 4 or unclassified lung cancer at diagnosis. Participants who develop lung cancer will be followed-up via electronic record-linkage to assess both time to diagnosis and stage of disease at diagnosis. The secondary outcomes are cost-effectiveness, and a range of psychological measurements. There is a nested qualitative study of the psychological effects test of results on participants.

**Results:** 10 280 high risk patients have been recruited to the end of December 2015 by GP mailing and self-referral other routes. 9.5% of the test group have a positive test, of these 207 have been found to have lung nodules > 8mm, 16 cancers have been detected, 12 of which are early stage and 11 abnormalities are undergoing further investigation detected to date in those who tested positive. No reliable control group data are available.

**Conclusions:** The study will determine the EarlyCDT-Lung test's clinical and cost effectiveness. It will also assess potential morbidity arising from the test and potential harms and benefits of a negative EarlyCDT-Lung test result. Early results are encouraging.